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(54) **MONITORING THE SEATING STATUS OF A FLUID RESERVOIR IN A FLUID INFUSION DEVICE**

(75) Inventors: **Afshin Bazargan**, Simi Valley, CA (US); **Pablo Vazquez**, Granada Hills, CA (US); **Hsiao-Yu S. Kow**, Ladera Ranch, CA (US); **Salman Monirabbasi**, Los Angeles, CA (US)

(73) Assignee: **Medtronic Minimed, Inc.**, Northridge, CA (US)

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See application file for complete search history.

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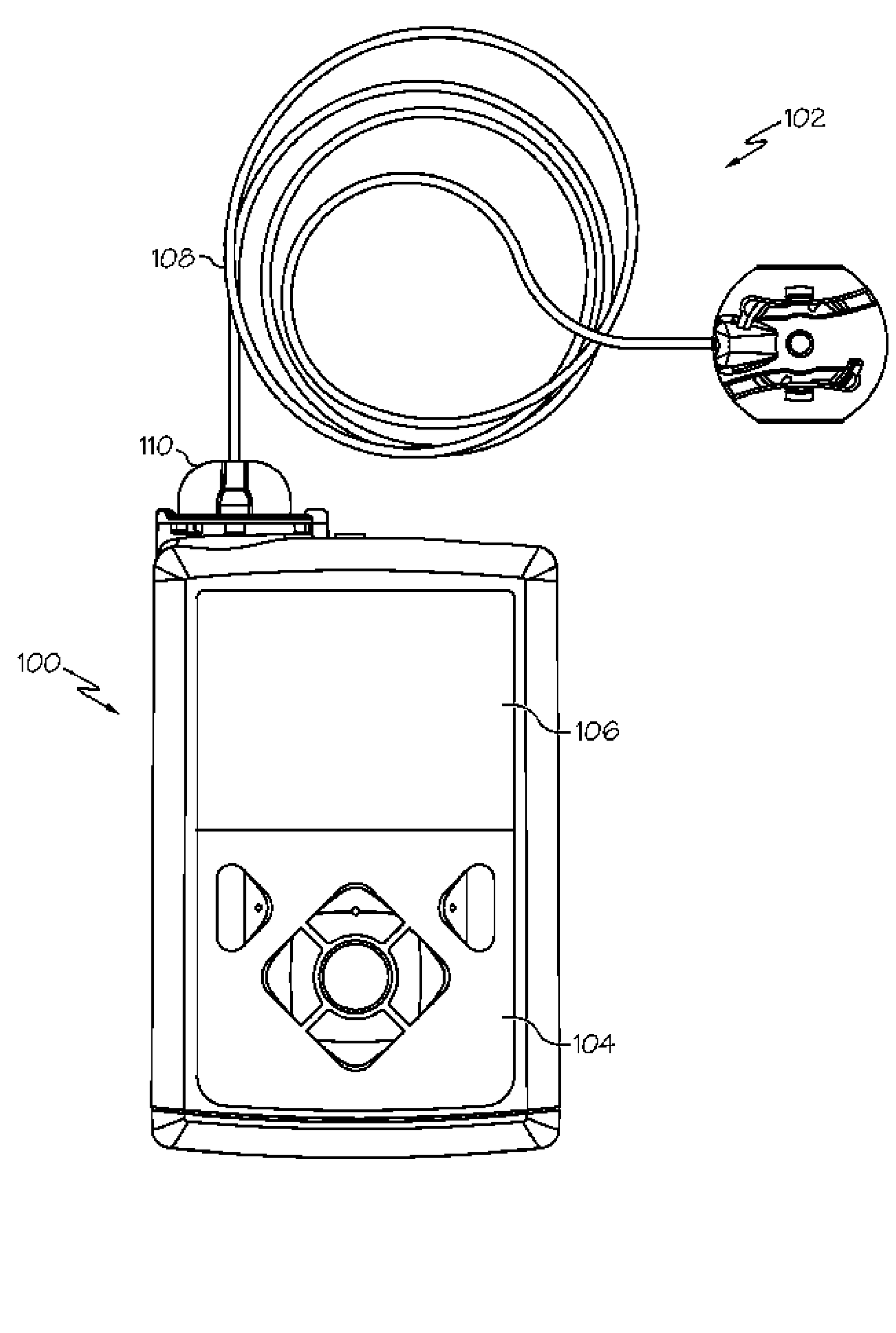
Primary Examiner — Nicholas Lucchesi
Assistant Examiner — Aarti B Berdichevsky
(74) *Attorney, Agent, or Firm* — Ingrassia Fisher & Lorenz, P.C.

(57) **ABSTRACT**

A device for delivering fluid to a user includes a housing, a drive motor assembly in the housing, a force sensor, and an electronics module. The drive motor assembly regulates delivery of fluid by actuating a piston of a fluid reservoir, and the force sensor generates output levels in response to force imparted thereto during, for example, fluid delivery operations. The electronics module processes the output levels of the force sensor to assess the operating health of the force sensor, to check for occlusions in the fluid delivery path, and to monitor the seating status of the fluid reservoir.

32 Claims, 12 Drawing Sheets



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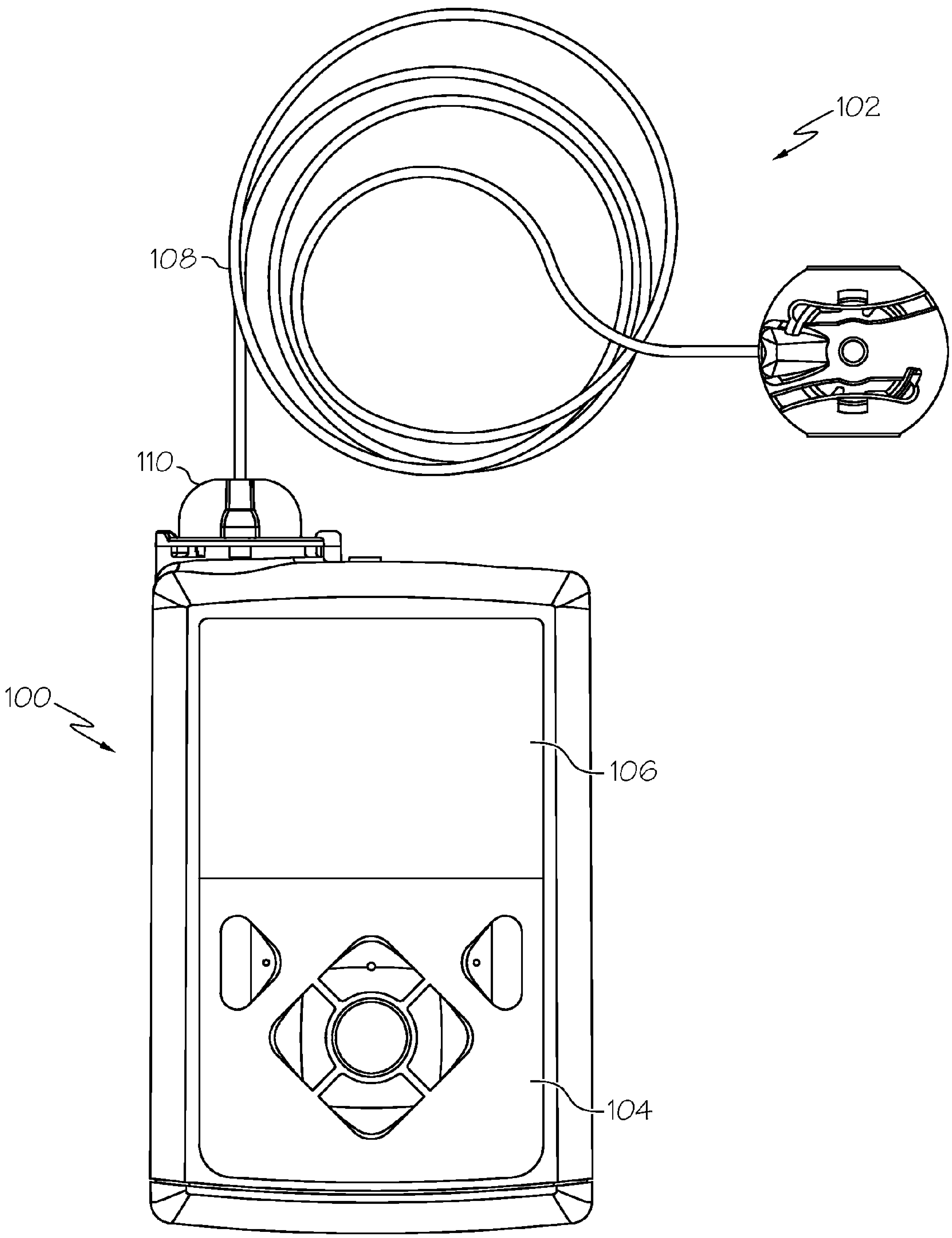
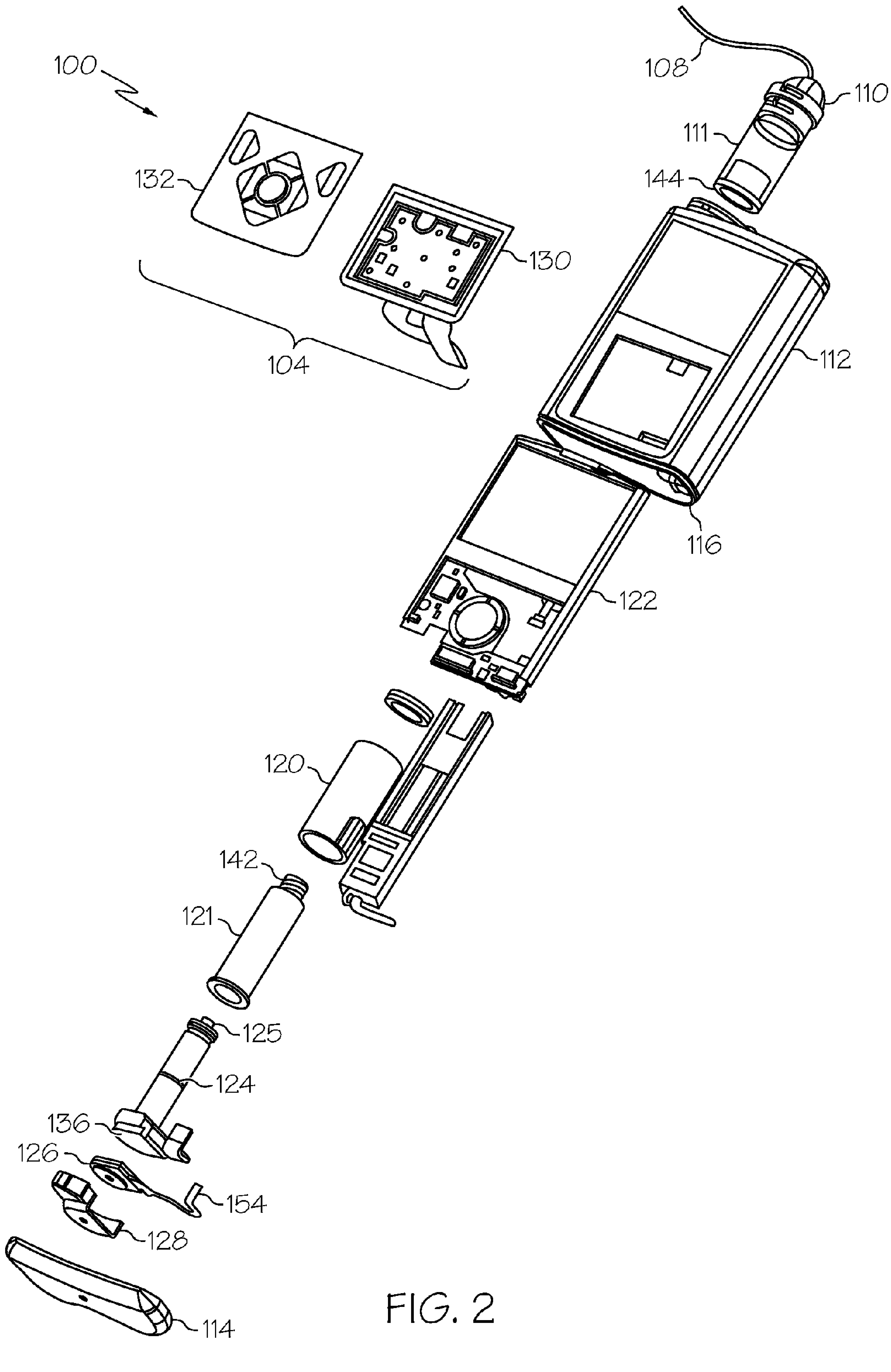


FIG. 1


100
108
110
111
144
132
130
104
112
116
122
120
142
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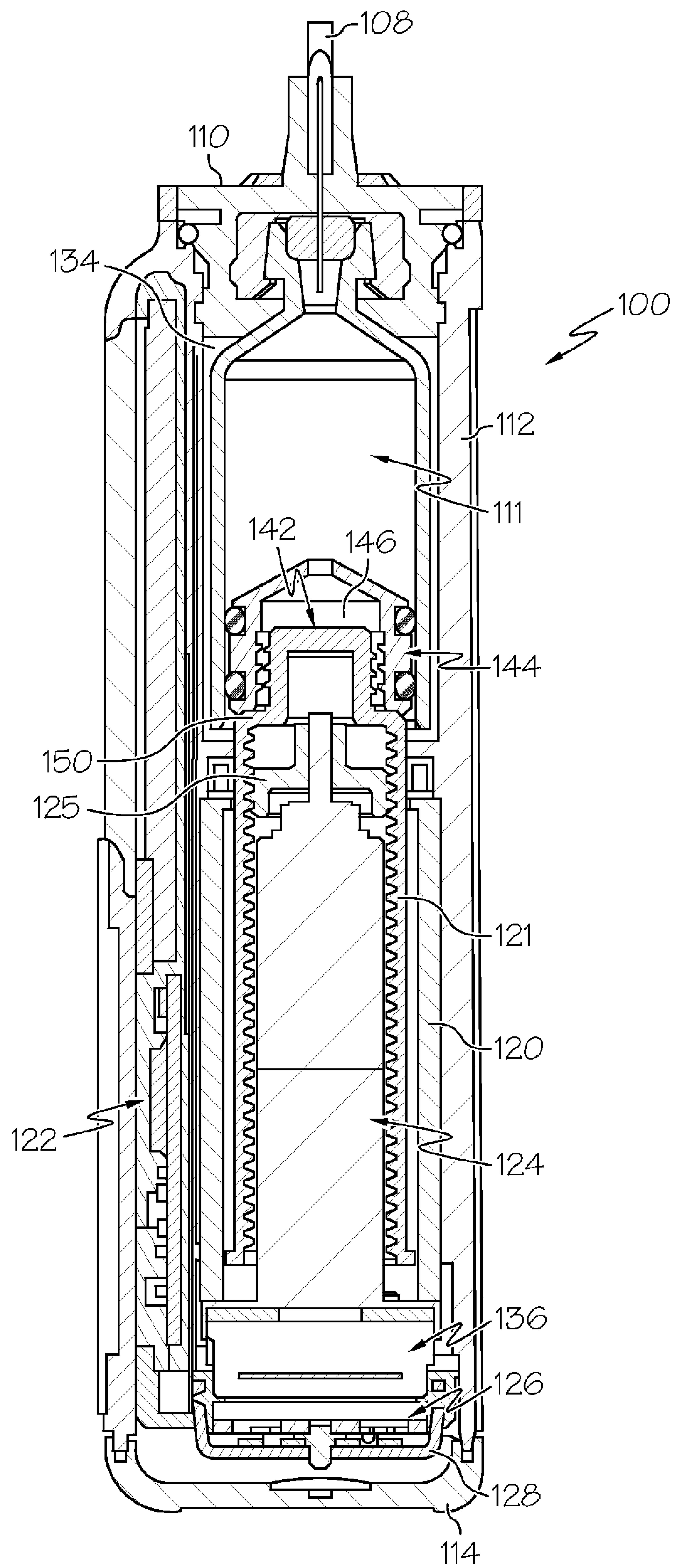
125
124
136
126
154
128
114

FIG. 2


108
110
134
100
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142
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144
150
125
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120
122
124
136
126
128
114

FIG. 3

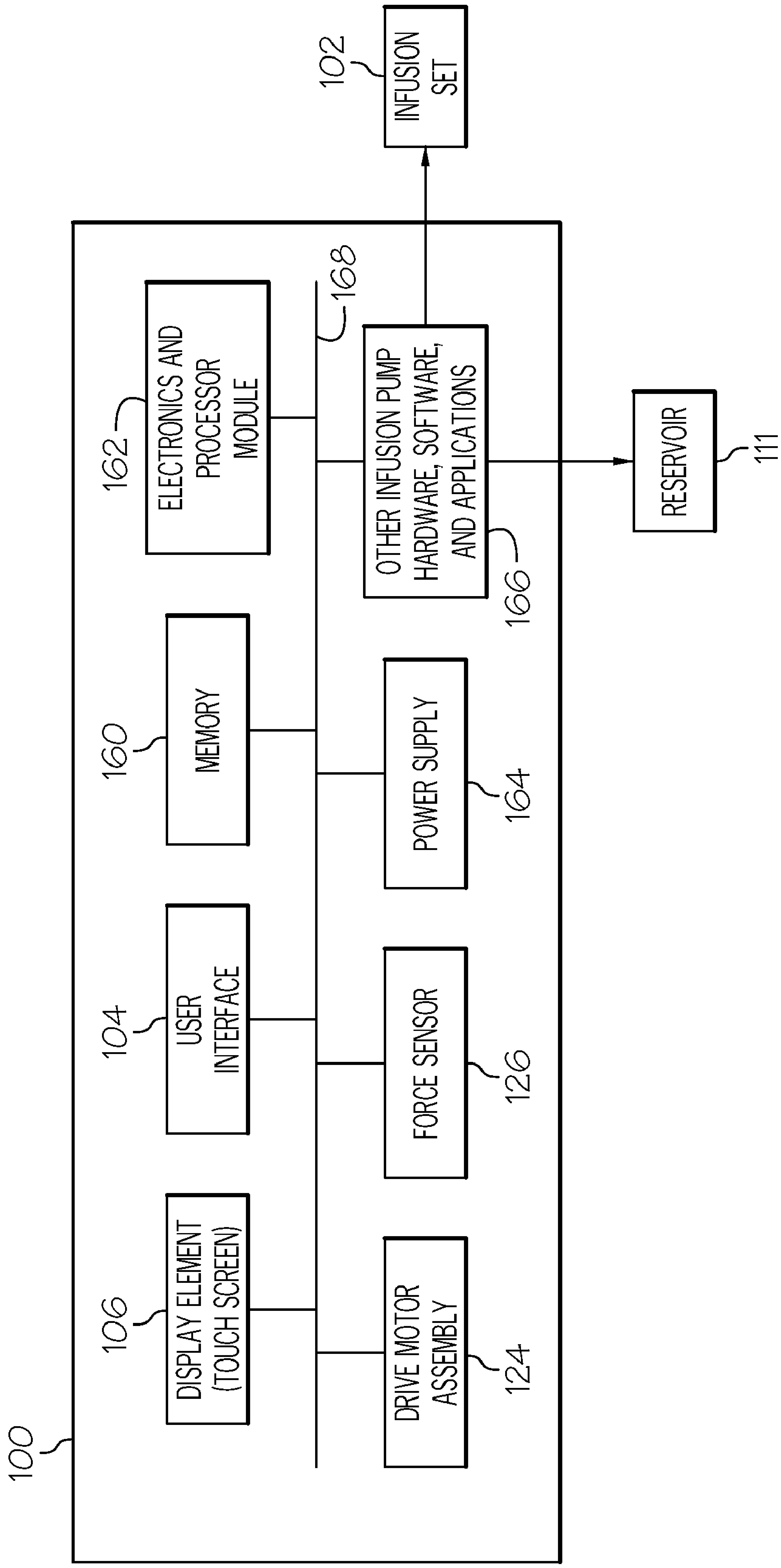
INFUSION SET
102
ELECTRONICS AND PROCESSOR MODULE
162
168
OTHER INFUSION PUMP HARDWARE, SOFTWARE, AND APPLICATIONS
166
RESERVOIR
111
MEMORY
160
POWER SUPPLY
164
USER INTERFACE
104
FORCE SENSOR
126
DISPLAY ELEMENT (TOUCH SCREEN)
106
DRIVE MOTOR ASSEMBLY
124
100

FIG. 4

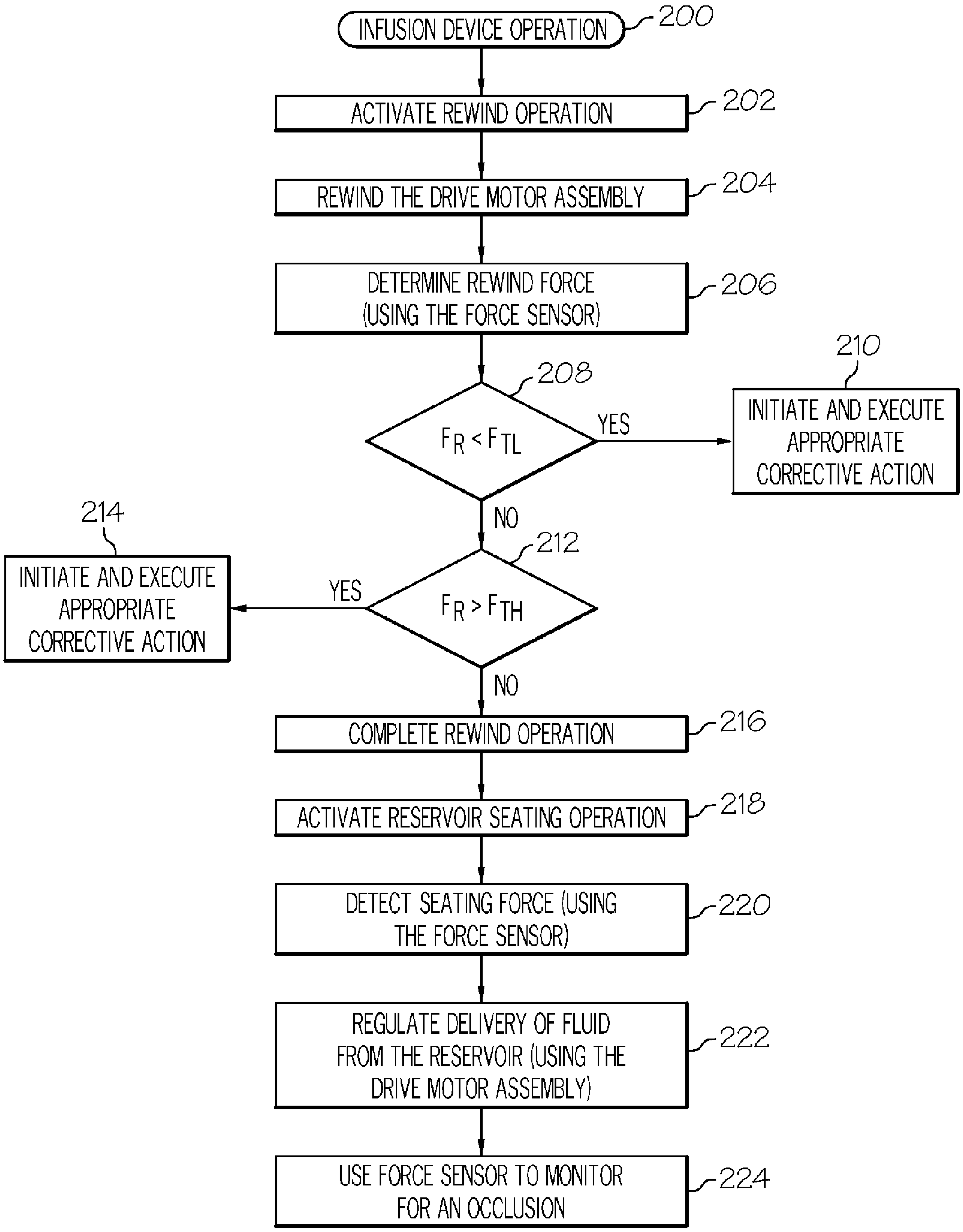
INFUSION DEVICE OPERATION
200
ACTIVATE REWIND OPERATION
202
REWIND THE DRIVE MOTOR ASSEMBLY
204
DETERMINE REWIND FORCE (USING THE FORCE SENSOR)
206
208
$F_R < F_{TL}$
YES
210
INITIATE AND EXECUTE APPROPRIATE CORRECTIVE ACTION
NO
212
$F_R > F_{TH}$
YES
214
INITIATE AND EXECUTE APPROPRIATE CORRECTIVE ACTION
NO
COMPLETE REWIND OPERATION
216
ACTIVATE RESERVOIR SEATING OPERATION
218
DETECT SEATING FORCE (USING THE FORCE SENSOR)
220
REGULATE DELIVERY OF FLUID FROM THE RESERVOIR (USING THE DRIVE MOTOR ASSEMBLY)
222
USE FORCE SENSOR TO MONITOR FOR AN OCCLUSION
224

FIG. 5

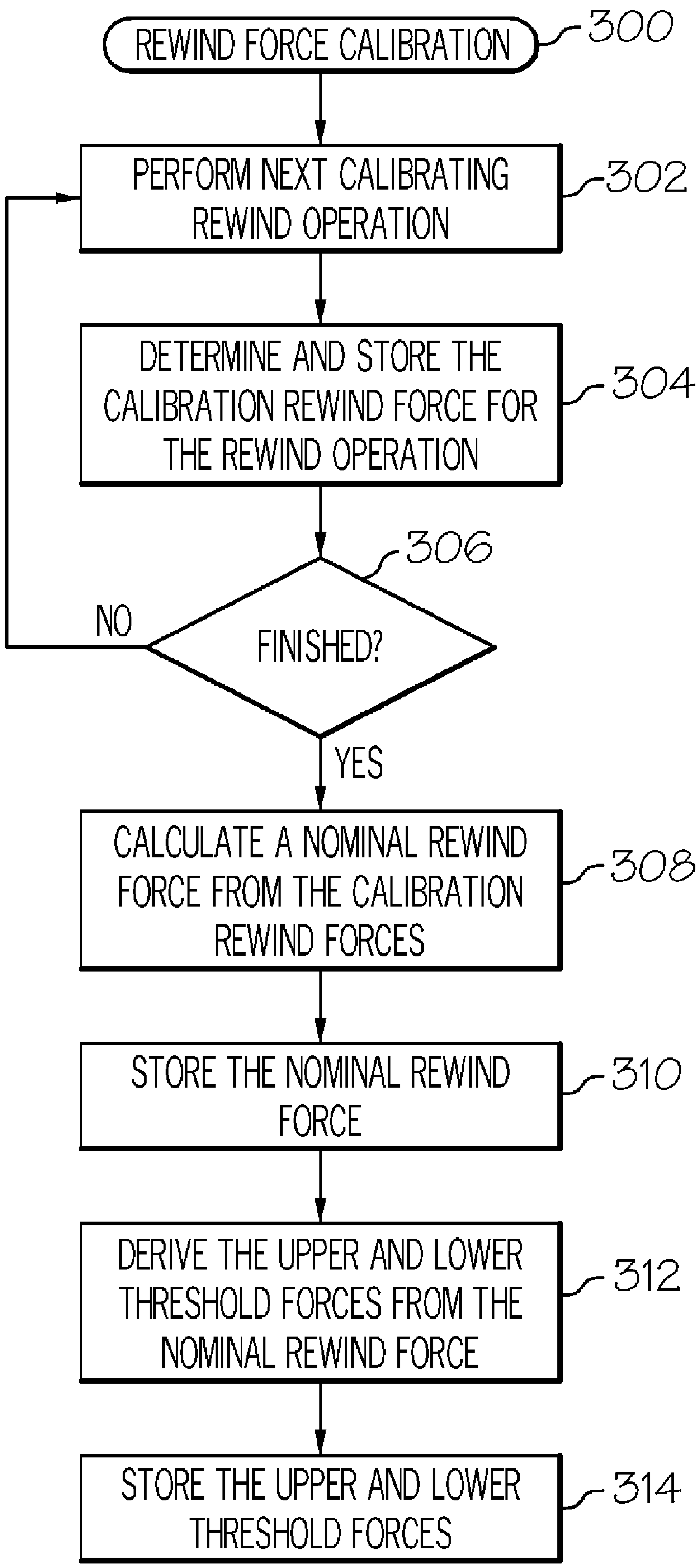
REWIND FORCE CALIBRATION
300
PERFORM NEXT CALIBRATING REWIND OPERATION
302
DETERMINE AND STORE THE CALIBRATION REWIND FORCE FOR THE REWIND OPERATION
304
306
NO
FINISHED?
YES
CALCULATE A NOMINAL REWIND FORCE FROM THE CALIBRATION REWIND FORCES
308
STORE THE NOMINAL REWIND FORCE
310
DERIVE THE UPPER AND LOWER THRESHOLD FORCES FROM THE NOMINAL REWIND FORCE
312
STORE THE UPPER AND LOWER THRESHOLD FORCES
314

FIG. 6

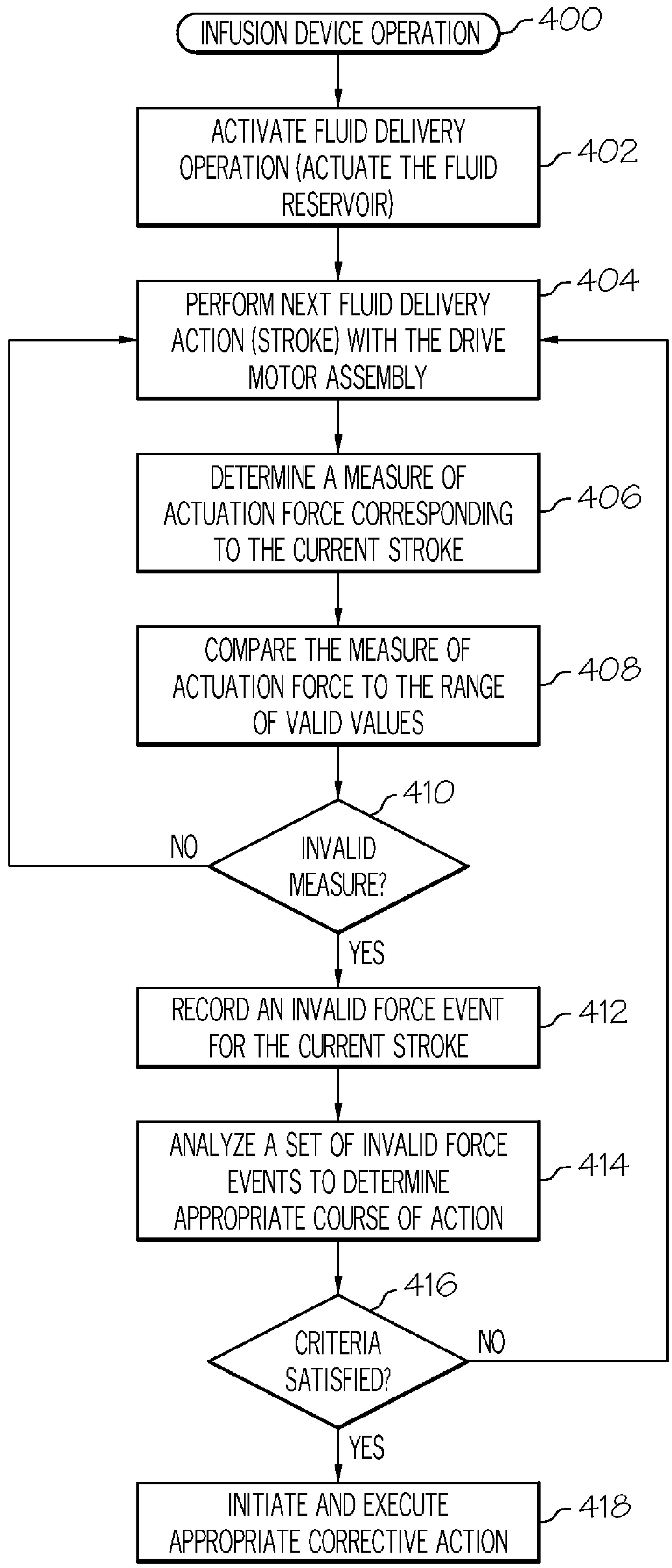
INFUSION DEVICE OPERATION
400
ACTIVATE FLUID DELIVERY OPERATION (ACTUATE THE FLUID RESERVOIR)
402
PERFORM NEXT FLUID DELIVERY ACTION (STROKE) WITH THE DRIVE MOTOR ASSEMBLY
404
DETERMINE A MEASURE OF ACTUATION FORCE CORRESPONDING TO THE CURRENT STROKE
406
COMPARE THE MEASURE OF ACTUATION FORCE TO THE RANGE OF VALID VALUES
408
INVALID MEASURE?
410
NO
YES
RECORD AN INVALID FORCE EVENT FOR THE CURRENT STROKE
412
ANALYZE A SET OF INVALID FORCE EVENTS TO DETERMINE APPROPRIATE COURSE OF ACTION
414
CRITERIA SATISFIED?
416
NO
YES
INITIATE AND EXECUTE APPROPRIATE CORRECTIVE ACTION
418

FIG. 7

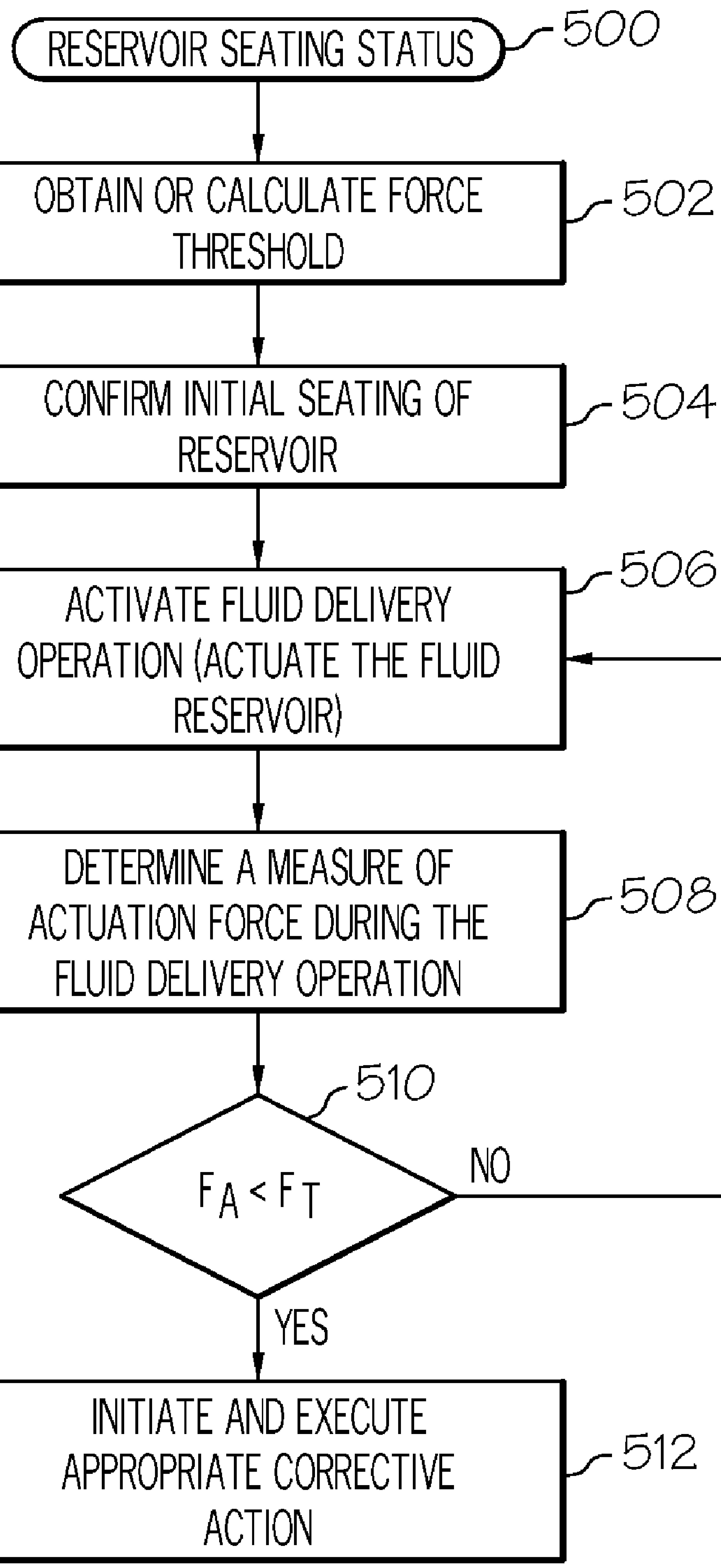
RESERVOIR SEATING STATUS
500
OBTAIN OR CALCULATE FORCE THRESHOLD
502
CONFIRM INITIAL SEATING OF RESERVOIR
504
ACTIVATE FLUID DELIVERY OPERATION (ACTUATE THE FLUID RESERVOIR)
506
DETERMINE A MEASURE OF ACTUATION FORCE DURING THE FLUID DELIVERY OPERATION
508
510
$F_A < F_T$
NO
YES
INITIATE AND EXECUTE APPROPRIATE CORRECTIVE ACTION
512

FIG. 8

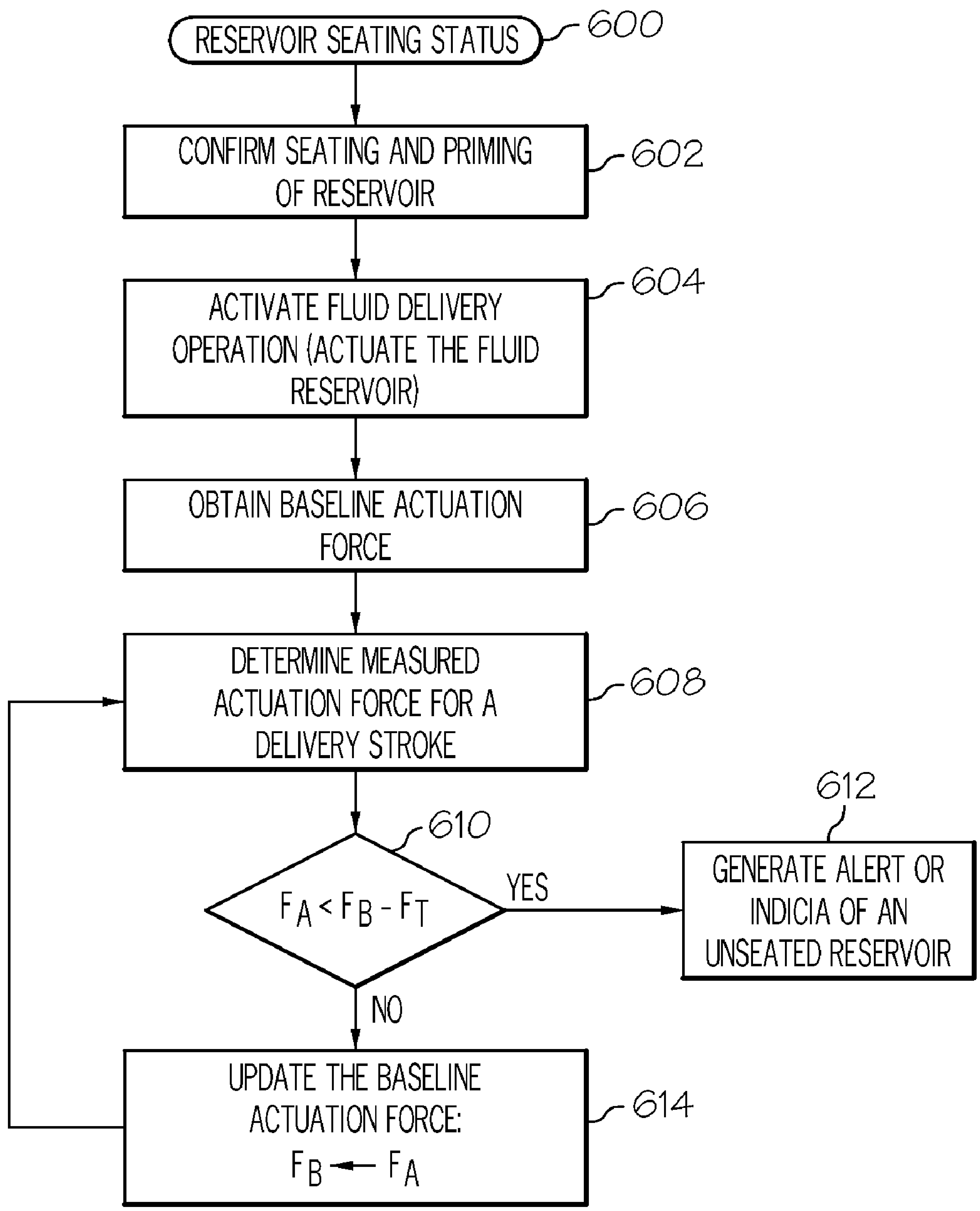
RESERVOIR SEATING STATUS
600
CONFIRM SEATING AND PRIMING OF RESERVOIR
602
ACTIVATE FLUID DELIVERY OPERATION (ACTUATE THE FLUID RESERVOIR)
604
OBTAIN BASELINE ACTUATION FORCE
606
DETERMINE MEASURED ACTUATION FORCE FOR A DELIVERY STROKE
608
610
$F_A < F_B - F_T$
YES
NO
612
GENERATE ALERT OR INDICIA OF AN UNSEATED RESERVOIR
UPDATE THE BASELINE ACTUATION FORCE:
$F_B \leftarrow F_A$
614

FIG. 9

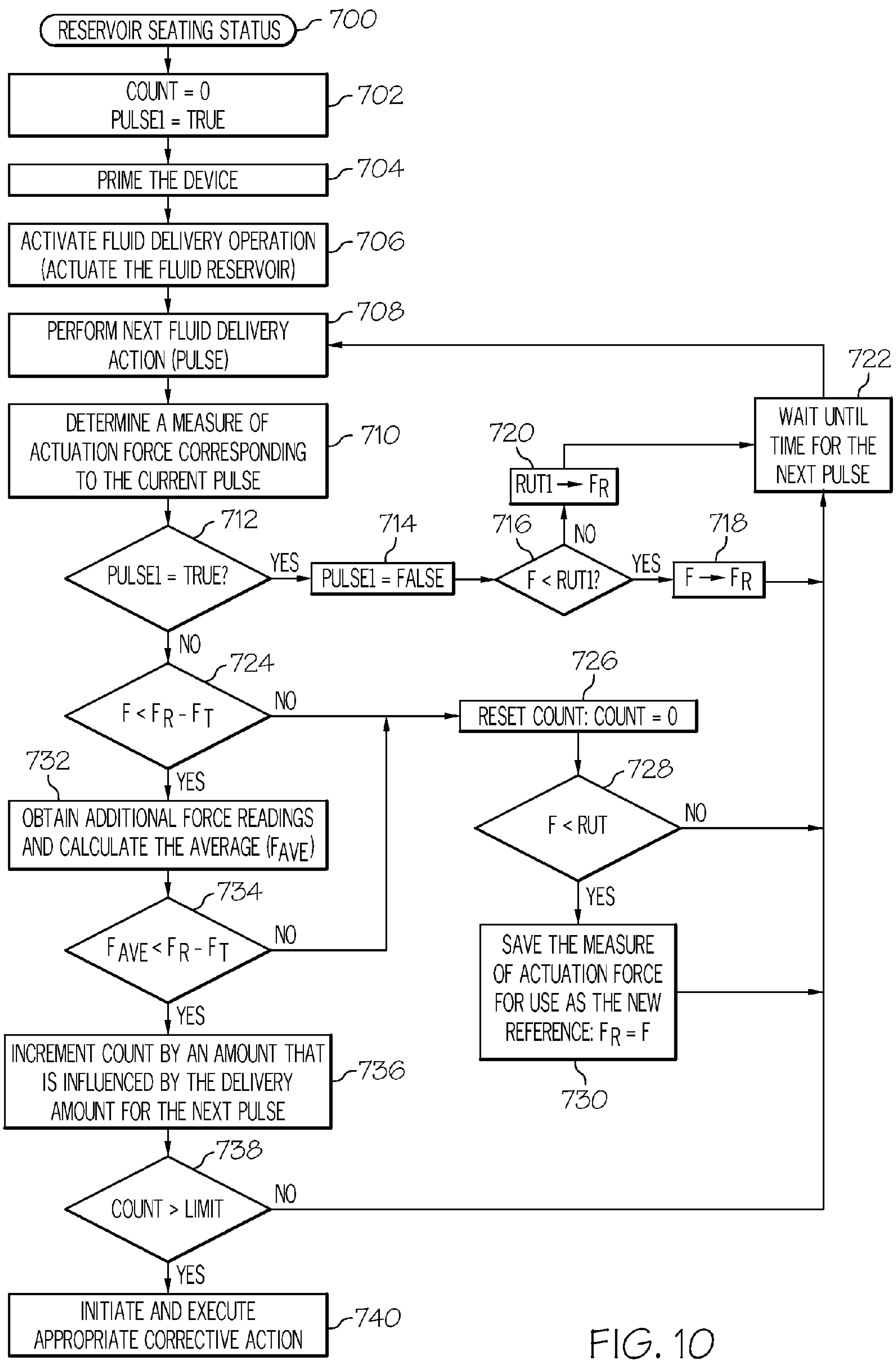
RESERVOIR SEATING STATUS
700
COUNT = 0
PULSE1 = TRUE
702
PRIME THE DEVICE
704
ACTIVATE FLUID DELIVERY OPERATION (ACTUATE THE FLUID RESERVOIR)
706
PERFORM NEXT FLUID DELIVERY ACTION (PULSE)
708
DETERMINE A MEASURE OF ACTUATION FORCE CORRESPONDING TO THE CURRENT PULSE
710
PULSE1 = TRUE?
712
YES
NO
PULSE1 = FALSE
714
F < RUT1?
716
NO
YES
RUT1 → FR
720
F → FR
718
WAIT UNTIL TIME FOR THE NEXT PULSE
722
F < FR - FT
724
NO
YES
RESET COUNT: COUNT = 0
726
F < RUT
728
NO
YES
SAVE THE MEASURE OF ACTUATION FORCE FOR USE AS THE NEW REFERENCE: FR = F
730
OBTAIN ADDITIONAL FORCE READINGS AND CALCULATE THE AVERAGE (FAVE)
732
FAVE < FR - FT
734
NO
YES
INCREMENT COUNT BY AN AMOUNT THAT IS INFLUENCED BY THE DELIVERY AMOUNT FOR THE NEXT PULSE
736
COUNT > LIMIT
738
NO
YES
INITIATE AND EXECUTE APPROPRIATE CORRECTIVE ACTION
740

FIG. 10

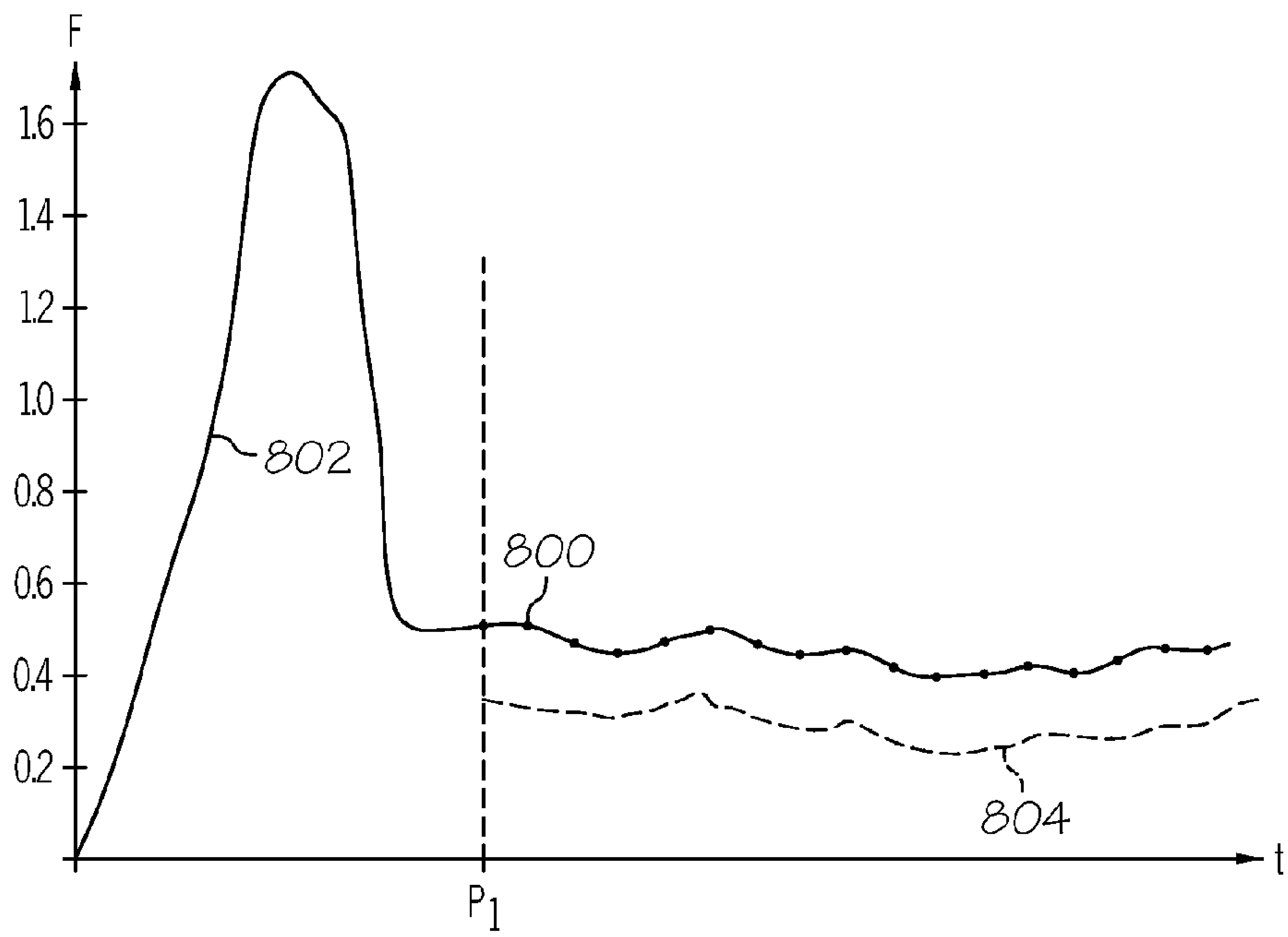
F
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
802
800
804
P1
t

FIG. 11

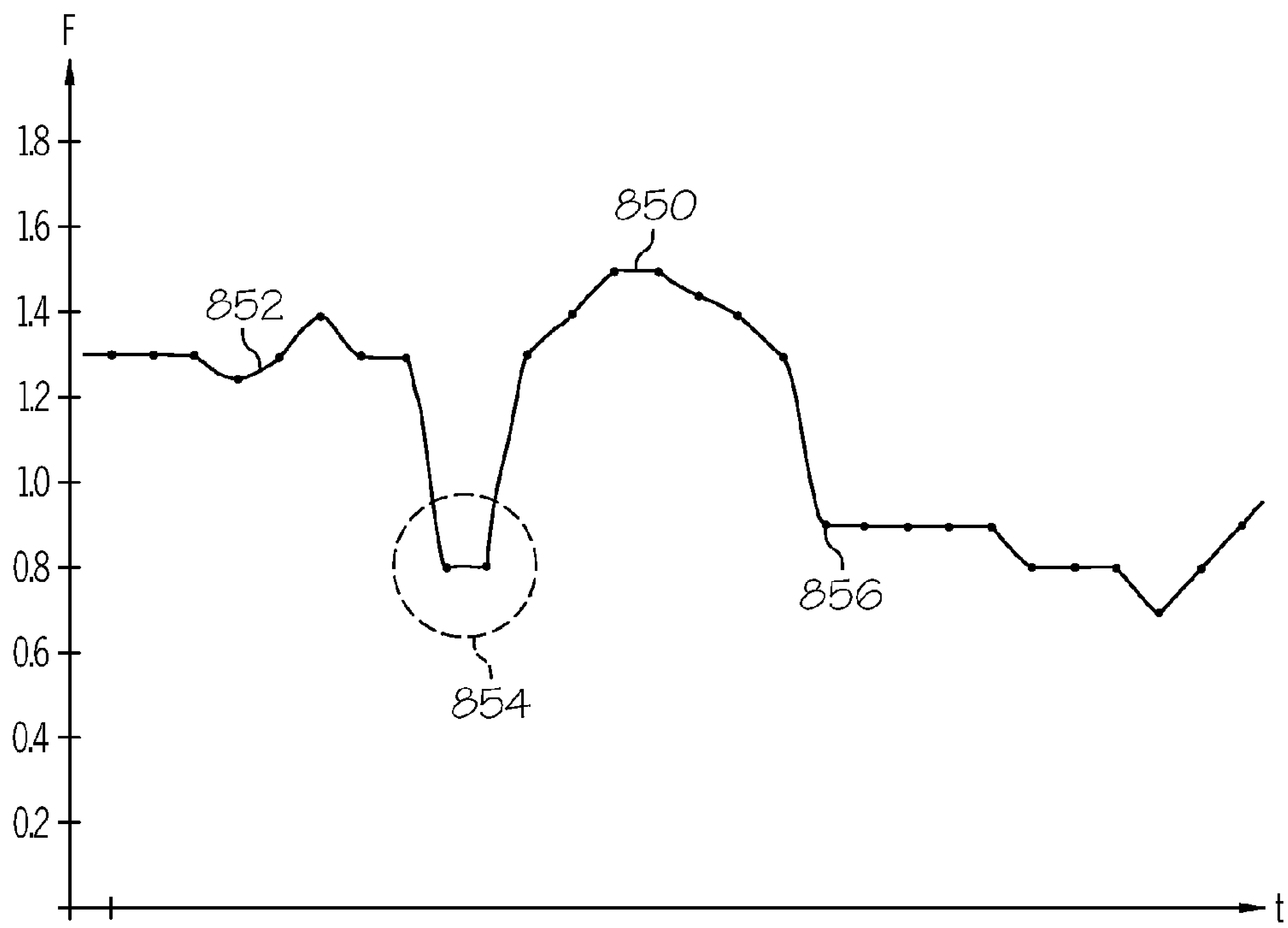
F
1.8
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
850
852
854
856
t

FIG. 12

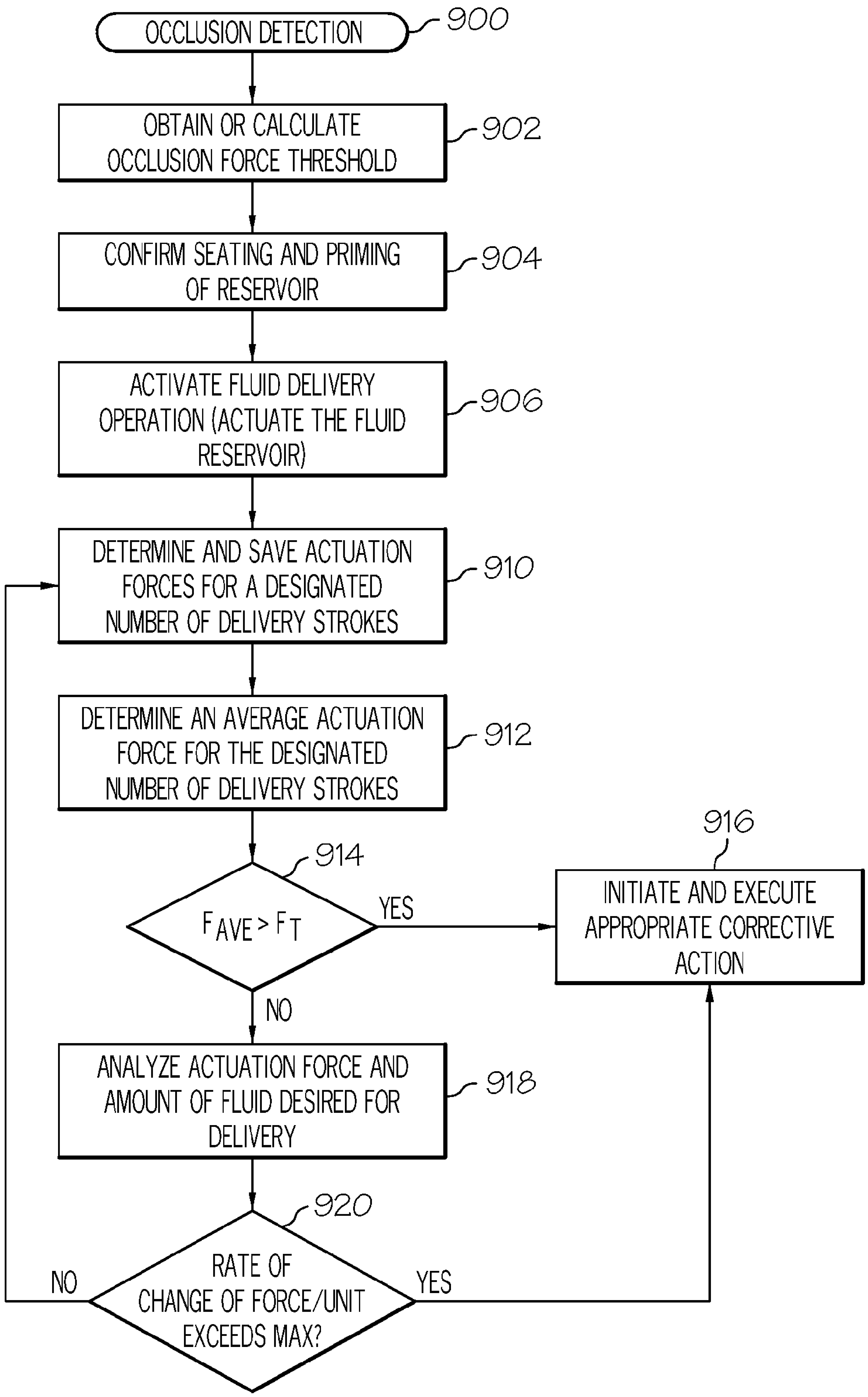
OCCLUSION DETECTION
900
OBTAIN OR CALCULATE OCCLUSION FORCE THRESHOLD
902
CONFIRM SEATING AND PRIMING OF RESERVOIR
904
ACTIVATE FLUID DELIVERY OPERATION (ACTUATE THE FLUID RESERVOIR)
906
DETERMINE AND SAVE ACTUATION FORCES FOR A DESIGNATED NUMBER OF DELIVERY STROKES
910
DETERMINE AN AVERAGE ACTUATION FORCE FOR THE DESIGNATED NUMBER OF DELIVERY STROKES
912
914
$F_{AVE} > F_T$
YES
916
INITIATE AND EXECUTE APPROPRIATE CORRECTIVE ACTION
NO
ANALYZE ACTUATION FORCE AND AMOUNT OF FLUID DESIRED FOR DELIVERY
918
920
NO
RATE OF CHANGE OF FORCE/UNIT EXCEEDS MAX?
YES

FIG. 13

MONITORING THE SEATING STATUS OF A FLUID RESERVOIR IN A FLUID INFUSION DEVICE

CROSS-REFERENCE TO RELATED APPLICATION(S)

The subject matter described here is related to the subject matter described in U.S. patent application Ser. No. 12/976, 591.

TECHNICAL FIELD

Embodiments of the subject matter described herein relate generally to medical devices. More particularly, embodiments of the subject matter relate to fluid infusion devices such as personal insulin infusion pumps.

BACKGROUND

Portable medical devices are useful for patients that have conditions that must be monitored on a continuous or frequent basis. For example, diabetics are usually required to modify and monitor their daily lifestyle to keep their blood glucose (BG) in balance. Individuals with Type 1 diabetes and some individuals with Type 2 diabetes use insulin to control their BG levels. To do so, diabetics routinely keep strict schedules, including ingesting timely nutritious meals, partaking in exercise, monitoring BG levels daily, and adjusting and administering insulin dosages accordingly.

The prior art includes a number of fluid infusion devices and insulin pump systems that are designed to deliver accurate and measured doses of insulin via infusion sets (an infusion set delivers the insulin through a small diameter tube that terminates at, e.g., a cannula inserted under the patient's skin). In lieu of a syringe, the patient can simply activate the insulin pump to administer an insulin bolus as needed, for example, in response to the patient's high BG level.

A typical infusion pump includes a housing, which encloses a pump drive system, a fluid containment assembly, an electronics system, and a power supply. The pump drive system typically includes a small motor (DC, stepper, solenoid, or other varieties) and drive train components such as gears, screws, and levers that convert rotational motor motion to a translational displacement of a stopper in a reservoir. The fluid containment assembly typically includes the reservoir with the stopper, tubing, and a catheter or infusion set to create a fluid path for carrying medication from the reservoir to the body of a user. The electronics system regulates power from the power supply to the motor. The electronics system may include programmable controls to operate the motor continuously or at periodic intervals to obtain a closely controlled and accurate delivery of the medication over an extended period.

Some fluid infusion devices use sensors and alarm features designed to detect and indicate certain operating conditions, such as non-delivery of the medication to the patient due to a fluid path occlusion. In this regard, a force sensor can be used in a fluid infusion device to detect when the force applied to the fluid reservoir stopper reaches a set point. The force sensor in such a fluid infusion device could be positioned at the end of the drive motor assembly that actuates a rotatable lead screw, which in turn advances the stopper of the reservoir. With such an arrangement, the force applied to the force sensor by the drive motor assembly is proportional to the pressure applied to the medication as a result of power supplied to the drive system to advance the stopper. Thus, when a certain force threshold (a set point corresponding to an occlusion condition) is reached, the fluid infusion device is triggered to generate an alarm to warn the user.

Early detection of an occlusion condition is helpful, because an occlusion can result in "under-dosing," particularly if the drive system continues to receive commands to deliver medication when the fluid path is blocked. Accordingly, proper operation of the force sensor is important for purposes of occlusion detection, and it is desirable to have some diagnostic capability related to the health of the force sensor.

Existing force-based occlusion detection techniques typically rely on a fixed threshold or set point that is indicative of an occlusion condition. A threshold value is selected based on system tolerances. To avoid frequent false alarms, however, it is necessary to set the threshold value above the maximum expected force, based on the interacting system components. Because the threshold value is set at the maximum expected force, if a patient has a particular pump system with a nominal delivery force, it may take slightly longer to reach the threshold force. Accordingly, it is desirable to have an occlusion detection technique that does not solely rely on a fixed occlusion detection threshold force.

Some fluid infusion devices use replaceable fluid reservoirs that are secured in the housing of the device and actuated by a drive assembly. One form of infusion pump utilizes a threaded cap to seat and secure the fluid reservoir in the housing of the pump. The user unscrews the threaded cap to remove an empty reservoir, replaces the old reservoir with a new reservoir, and reinstalls the threaded cap to secure the new reservoir in place. During use, the threaded cap might be dislodged (especially if the fluid infusion device is a portable unit that is worn by the patient), resulting in an unseated or improperly installed reservoir. For example, if the user participates in certain physical activities (e.g., sports, hiking, or rigorous exercise), then the cap might be unintentionally loosened by physical rotation. As another example, if the user is in a crowded environment (e.g., a concert, a nightclub, or a full elevator), then the cap might be inadvertently unscrewed through contact with another person or an object. For this reason, it is desirable to have a reservoir presence and/or seating detection technique for a fluid infusion pump.

BRIEF SUMMARY

A method of operating a fluid infusion device is provided. The fluid infusion device includes a drive motor assembly and a force sensor associated with the drive motor assembly. The method activates a rewind operation of the drive motor assembly and determines a rewind force imparted to the force sensor during the rewind operation. The method initiates corrective action for the fluid infusion device when the rewind force is less than a lower threshold force or greater than an upper threshold force.

Also provided is an exemplary embodiment of a device for delivering fluid to a user. The device includes: a housing; a drive motor assembly in the housing to regulate delivery of fluid by actuating a piston of a fluid reservoir; a force sensor associated with the drive motor assembly to generate output levels in response to force imparted thereto; and an electronics module coupled to the force sensor to process the output levels to determine operating health of the force sensor.

Another embodiment of a method of operating a fluid infusion device is also provided. The fluid infusion device includes a drive motor assembly and a force sensor associated with the drive motor assembly. The method involves determining a measure of actuation force imparted to the force sensor during a fluid delivery action of the drive motor assembly, and comparing the measure of actuation force against a range of valid values that represents normally expected measures of actuation forces. When the measure of actuation force is outside the range of valid values, the method initiates corrective action for the fluid infusion device.

A method of determining a seating status of a fluid reservoir in the reservoir cavity of a fluid infusion device is also provided. The fluid infusion device includes a drive motor assembly, a force sensor associated with the drive motor assembly, and a reservoir cavity that accommodates fluid reservoirs. The method begins by confirming initial seating of the fluid reservoir in the reservoir cavity. The method continues by determining a measure of actuation force imparted to the force sensor during a fluid delivery action of the drive motor assembly, and comparing the measure of actuation force to an amount of force that is less than normally expected actuation forces of the fluid infusion device, where the amount of force is indicative of an unseated state of the fluid reservoir. The method continues by initiating corrective action for the fluid infusion device when the measure of actuation force is less than the amount of force.

A device for delivering fluid to a user is also provided. The device includes: a housing; a reservoir cavity within the housing to accommodate fluid reservoirs; a drive motor assembly in the housing to regulate delivery of fluid by actuating a piston of a fluid reservoir; a force sensor associated with the drive motor assembly to generate output levels in response to force imparted thereto; and an electronics module coupled to the force sensor to process the output levels to determine a seating status of the fluid reservoir in the reservoir cavity.

Another embodiment of a method of determining a seating status of a fluid reservoir in the reservoir cavity of a fluid infusion device is provided. The method obtains baseline actuation force imparted to a force sensor, after initial seating and priming of the fluid reservoir. The method continues by determining a measured actuation force imparted to the force sensor, the measured actuation force corresponding to a designated delivery stroke of the drive motor assembly. The method also generates indicia of an unseated reservoir condition when the measured actuation force is less than the baseline actuation force by at least a predetermined amount of force.

Also provided is a method of determining a seating status of a fluid reservoir in a fluid infusion device having a drive motor assembly that actuates the fluid reservoir using discrete delivery pulses. The method obtains measures of actuation force imparted to the force sensor for a number of consecutive fluid delivery pulses, and calculates a pulse-to-pulse difference between consecutive fluid delivery pulses, the pulse-to-pulse difference based on respective measures of actuation force for the consecutive fluid delivery pulses. The method continues by initiating corrective action for the fluid infusion device when the pulse-to-pulse difference is greater than a threshold force value.

Another embodiment of a method of determining a seating status of a fluid reservoir in a fluid infusion device is provided. The infusion device has a drive motor assembly that actuates the fluid reservoir using discrete delivery pulses, and the method involves: maintaining a count that is indicative of the seating status; storing an adaptive reference force value that corresponds to a previously recorded measure of actuation force imparted to the force sensor during a previous fluid delivery pulse; obtaining a current measure of actuation force imparted to the force sensor for a current fluid delivery pulse; changing the count when the current measure of actuation force is less than the difference between the adaptive reference force value and a threshold force value, resulting in an updated count; and generating a seating status alert when the updated count satisfies predetermined alert criteria.

This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the detailed description. This summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the subject matter may be derived by referring to the detailed description and claims when considered in conjunction with the following figures, wherein like reference numbers refer to similar elements throughout the figures.

FIG. **1** is a schematic representation of an embodiment of a fluid infusion device;

FIG. **2** is an exploded perspective view of the fluid infusion device shown in FIG. **1**;

FIG. **3** is a cross sectional view of the fluid infusion device shown in FIG. **1**, corresponding to a cross section taken longitudinally through the drive motor assembly and the fluid reservoir;

FIG. **4** is a schematic block diagram representation of an embodiment of a fluid infusion device;

FIG. **5** is a flow chart that illustrates an embodiment of a process associated with the operation of a fluid infusion device;

FIG. **6** is a flow chart that illustrates an embodiment of a rewind force calibration process for a fluid infusion device;

FIG. **7** is a flow chart that illustrates another embodiment of a process associated with the operation of a fluid infusion device;

FIG. **8** is a flow chart that illustrates an embodiment of a process that checks the seating status of a fluid reservoir of a fluid infusion device;

FIG. **9** is a flow chart that illustrates another embodiment of a process that checks the seating status of a fluid reservoir of a fluid infusion device;

FIG. **10** is a flow chart that illustrates yet another embodiment of a process that checks the seating status of a fluid reservoir of a fluid infusion device;

FIG. **11** is a graph that illustrates measures of actuation forces for a properly seated fluid reservoir;

FIG. **12** is a graph that illustrates measures of actuation forces for a fluid reservoir that becomes unseated; and

FIG. **13** is a flow chart that illustrates an embodiment of an occlusion detection process for a fluid infusion device.

DETAILED DESCRIPTION

The following detailed description is merely illustrative in nature and is not intended to limit the embodiments of the subject matter or the application and uses of such embodiments. As used herein, the word "exemplary" means "serving as an example, instance, or illustration." Any implementation described herein as exemplary is not necessarily to be construed as preferred or advantageous over other implementations. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

Techniques and technologies may be described herein in terms of functional and/or logical block components, and with reference to symbolic representations of operations, processing tasks, and functions that may be performed by various computing components or devices. It should be appreciated that the various block components shown in the figures may be realized by any number of hardware, software, and/or firmware components configured to perform the specified functions. For example, an embodiment of a system or a component may employ various integrated circuit components, e.g., memory elements, digital signal processing elements, logic elements, look-up tables, or the like, which may carry out a variety of functions under the control of one or more microprocessors or other control devices.

For the sake of brevity, conventional techniques related to infusion system operation, insulin pump and/or infusion set operation, blood glucose sensing and monitoring, force sensors, signal processing, and other functional aspects of the systems (and the individual operating components of the systems) may not be described in detail here. Examples of infusion pumps and/or related pump drive systems used to administer insulin and other medications may be of the type described in, but not limited to, U.S. Pat. Nos. 4,562,751; 4,678,408; 4,685,903; 5,080,653; 5,505,709; 5,097,122; 6,485,465; 6,554,798; 6,558,351; 6,659,980; 6,752,787; 6,817,990; 6,932,584; and 7,621,893; which are herein incorporated by reference.

The subject matter described here relates to a fluid infusion device of the type used to treat a medical condition of a patient. The infusion device is used for infusing fluid into the body of a user. The non-limiting examples described below relate to a medical device used to treat diabetes (more specifically, an insulin pump), although embodiments of the disclosed subject matter are not so limited. Accordingly, the infused fluid is insulin in certain embodiments. In alternative embodiments, however, many other fluids may be administered through infusion such as, but not limited to, disease treatments, drugs to treat pulmonary hypertension, iron chelation drugs, pain medications, anti-cancer treatments, medications, vitamins, hormones, or the like.

A methodology for monitoring the operational health of a sensor (e.g., a force sensor) is implemented by an exemplary embodiment of a fluid infusion device. The fluid infusion device monitors force measurements obtained from the force sensor during a motor rewind operation to determine whether or not the force sensor might be out of calibration, on the verge of failure, or the like. The force normally experienced by the force sensor during rewind operations should be zero or close to zero, due to the absence of a fluid reservoir in the fluid infusion device, and because the fluid infusion device is driving in rewind mode, i.e., away from the plunger of the fluid reservoir. Accordingly, the fluid infusion device can assume that a properly functioning force sensor will produce rewind force readings in the neighborhood of zero or close to zero. Thus, if a rewind force measurement significantly deviates from the assumed baseline value (or range of values), then the fluid infusion device can take appropriate corrective action.

Another methodology for monitoring the operational health of a force sensor obtains force readings during a fluid delivery operation and compares the force readings to determine whether or not the force sensor is operating as expected. This alternate methodology measures the forces associated with individual fluid delivery strokes or drive motor pulses. Under normal and typical operating conditions, these forces will be relatively stable during one fluid delivery operation, and the variation from one stroke to another will be slight (absent an external impact or shock suffered by the fluid infusion device). Thus, if the force sensor reading is out of the expected operating range during a fluid delivery operation, the fluid infusion device can take appropriate corrective action. For example, if the force sensor output during fluid delivery happens to be −0.5 pounds, then clearly there is a problem because in reality the measured force should not be a negative value.

A fluid infusion device may also have an occlusion detection feature that determines when the fluid delivery path is occluded. Occlusion detection techniques are usually based on sensor measurements (force, pressure, stress) that are influenced by the flow status of the fluid delivery path. An exemplary embodiment of a fluid infusion device as described here employs an adaptive occlusion detection technique that need not rely on a fixed occlusion detection force threshold. Instead, the adaptive occlusion detection technique evaluates the rate of change of a metric associated with force variations per units of fluid to be delivered. For example, the typical force variation for a fluid reservoir might result in a variation of about ±X pounds per unit (lb/U) over a set number of delivery strokes (or drive motor pulses). If, however, the fluid infusion device detects a significant increase in this metric during a fluid delivery operation (e.g., ±Y lb/U, where Y is significantly larger than X) over the same set number of delivery strokes, then the fluid infusion device can take appropriate corrective action. The values of X and Y can also be in units of lb/pulse or the like. An example of a corrective action might be, but not limited to, immediately indicate or warn of an occlusion or simply lower the set threshold value by a set constant or percentage and allow the pump to continue delivery for a set number of pulses or units to see if the pump recovers (recovery might occur in the case of a kinked cannula). The adaptive occlusion detection methodology allows the fluid infusion device to determine the existence of an occlusion much quicker, relative to a fixed threshold based methodology. Quicker occlusion detection is made possible because the fluid infusion device need not be operated until a high threshold force is reached; rather, occlusion can be detected earlier without having to wait for a high force condition.

An exemplary embodiment of a fluid infusion device may also be configured to determine whether or not a fluid reservoir is properly seated and installed. The presence (or lack thereof) of the fluid reservoir is determined based upon force sensor readings that are obtained after proper initial installation and seating of the fluid reservoir. In accordance with one embodiment, one or more force thresholds are used to determine whether or not the fluid reservoir is properly seated. If a measured force does not satisfy a force threshold that is indicative of proper reservoir seating, then the fluid infusion device can take corrective action. In accordance with another exemplary embodiment, the fluid infusion device measures and processes the forces associated with individual fluid delivery strokes or drive motor pulses to determine when the fluid reservoir has been dislodged, removed, or unseated.

FIG. **1** is a plan view of an exemplary embodiment of a fluid infusion device **100**. FIG. **1** also shows an infusion set **102** coupled to the fluid infusion device **100**. The fluid infusion device **100** is designed to be carried or worn by the patient. The fluid infusion device **100** may leverage a number of conventional features, components, elements, and characteristics of existing fluid infusion devices. For example, the fluid infusion device **100** may incorporate some of the features, components, elements, and/or characteristics described in U.S. Pat. Nos. 6,485,465 and 7,621,893, the relevant content of which is incorporated by reference herein.

This embodiment shown in FIG. **1** includes a user interface **104** that includes several buttons that can be activated by the user. These buttons can be used to administer a bolus of insulin, to change therapy settings, to change user preferences, to select display features, and the like. Although not required, the illustrated embodiment of the fluid infusion device **100** includes a display element **106**. The display element **106** can be used to present various types of information or data to the user, such as, without limitation: the current glucose level of the patient; the time; a graph or chart of the patient's glucose level versus time; device status indicators; etc. In some embodiments, the display element **106** is realized as a touch screen display element and, therefore, the display element **106** also serves as a user interface component.

The fluid infusion device **100** accommodates a fluid reservoir (hidden from view in FIG. **1**) for the fluid to be delivered to the user. A length of tubing **108** is the flow path that couples the fluid reservoir to the infusion set **102**. The tubing **108** extends from the fluid infusion device **100** to the infusion set **102**, which provides a fluid pathway with the body of the user. A removable cap or fitting **110** is suitably sized and configured to accommodate replacement of fluid reservoirs (which are typically disposable) as needed. In this regard, the fitting **110** is designed to accommodate the fluid path from the fluid reservoir to the tubing **108**.

FIG. **2** is an exploded perspective view of the fluid infusion device **100**. For the sake of brevity and simplicity, FIG. **2** is a simplified depiction of the fluid infusion device **100** that does not include all of the elements, components, and features that would otherwise be present in a typical embodiment. It should be appreciated that a deployed implementation of the fluid infusion device **100** will include additional features, components, and elements that are not shown in the figures.

The embodiment of the fluid infusion device **100** illustrated in FIG. **2** includes a housing **112** and a housing end cap **114** that is coupled to an end **116** of the housing **112** to enclose components within the housing **112**. These internal components include, without limitation: a battery tube subassembly **118**; a sleeve **120**; a slide **121**; an electronics assembly **122**; a drive motor assembly **124** having a drive screw **125**; a force sensor **126**; and a motor support cap **128**. FIG. **2** also depicts some components that are located outside the housing **112**, namely, a keypad assembly **130** and a graphic keypad overlay **132** for the keypad assembly **130**. The keypad assembly **130** and the graphic keypad overlay **132** may be considered to be part of the user interface **104** of the fluid infusion device **100**. The outer edge of the motor support cap **128** is attached to the interior side of the housing **112**, and the motor support cap **128** contacts the force sensor **126** to remove assembly tolerances from the drive motor assembly **124**. FIG. **2** also depicts an exemplary fluid reservoir **111**, which is inserted into a reservoir cavity defined within the housing **112**. The reservoir cavity is configured, sized, and shaped to accommodate fluid reservoirs, and the fluid reservoir **111** is maintained in the reservoir cavity using the fitting **110**. The electronics assembly **122** may include a suitably configured electronics module (not shown in FIG. **2**; see FIG. **4** and related description below), which may include or cooperate with a power supply, at least one memory element, at least one processor, processing logic, and device software, firmware, and application programs.

FIG. **3** is a cross sectional view of the fluid infusion device **100**, corresponding to a cross section taken longitudinally through the drive motor assembly **124** and the fluid reservoir **111**. FIG. **3** depicts the state of the fluid infusion device **100** after the fluid reservoir **111** has been inserted into the reservoir cavity **134** and after the fitting **110** has been secured to the housing **112** to hold the fluid reservoir **111** in place. While certain embodiments accommodate disposable, prefilled reservoirs, alternative embodiments may use refillable cartridges, syringes or the like. A cartridge can be prefilled with insulin (or other drug or fluid) and inserted into the housing **112**. Alternatively, a cartridge could be filled by the user using an appropriate adapter and/or any suitable refilling device.

When assembled as shown in FIG. **3**, the drive motor assembly **124** is located in the housing **112**. The force sensor **126** is operatively associated with the drive motor assembly **124**. For this particular embodiment, the force sensor **126** is coupled to the drive motor assembly **124**, and it is located between a base end of the drive motor assembly **124** and the motor support cap **128**. In one implementation, the force sensor **126** is affixed to the base end of the drive motor assembly **124** such that the force sensor **126** reacts when it bears against the motor support cap **128**. In another implementation, the force sensor **126** is affixed to the housing end cap **114** such that the force sensor **126** reacts when the drive motor assembly **124** bears against the force sensor **126**. This configuration and arrangement of the drive motor assembly **124** and the force sensor **126** allows the force sensor **126** to react to forces imparted thereto by the drive motor assembly **124** and/or forces imparted to the drive motor assembly **124** via the fluid pressure of the fluid reservoir **111**.

The drive motor assembly **124** includes an electric motor **136** that is actuated and controlled by the electronics module of the fluid infusion device **100**. The motor **136** is preferably realized as a stepper motor that rotates in a stepwise or discrete manner corresponding to the desired number of fluid delivery strokes. Alternatively, the motor **136** could be a DC motor, a solenoid, or the like. The motor **136** may optionally include an encoder (not shown), which cooperates with the electronics module of the fluid infusion device **100** to monitor the number of motor rotations or portions thereof. This in turn can be used to accurately determine the position of the slide **121**, thus providing information relating to the amount of fluid dispensed from the fluid reservoir **111**.

The drive motor assembly **124** can be mounted in the housing **112** using an appropriate mounting feature, structure, or element. Alternatively, the mounting could be accomplished using a shaft bearing and leaf spring or other known compliance mountings.

The illustrated embodiment of the drive motor assembly **124** includes a drive member (such as the externally threaded drive gear or drive screw **125**) that engages an internally threaded second drive member (such as the slide **121**) having a coupler **142**. The coupler **142** may be attached to or integrated with the slide **121**, as depicted in FIG. **2** and FIG. **3**. The slide **121** is sized to fit within the housing of the fluid reservoir **111**, which enables the slide **121** to operatively cooperate with the fluid reservoir **111**. The fluid reservoir **111** includes a plunger or piston **144** with at least one sealing element or feature (e.g., one or more O-rings, integral raised ridges, or a washer) for forming a fluid and air tight seal with the inner wall of the fluid reservoir **111**. As mentioned previously, the fluid reservoir **111** is secured into the housing **112** with the fitting **110**, which also serves as the interface between the fluid reservoir **111** and the infusion set tubing **108**. For this embodiment, the piston **144** is in contact with a linear actuation member, such as the slide **121**. For example, the piston **144** may have a female portion **146** that receives the coupler **142** carried by the slide **121**. The female portion **146** is positioned at the end face of the piston **144**, and it is sized to receive and accommodate the coupler **142**. In certain embodiments, the female portion **146** includes a threaded cavity that engages external threads of the coupler **142**.

Referring to FIG. **3**, rotation of the drive shaft of the motor **136** results in corresponding rotation of the drive screw **125**, which in turn drives the slide **121** via the threaded engagement. Thus, rotation of the drive screw **125** results in axial displacement of the slide **121** and, therefore, axial displacement of the coupler **142**. Such displacement of the coupler **142** moves the piston **144** (upward in FIG. **3**) to deliver a predetermined or commanded amount of medication or liquid from the fluid infusion device **100**. In this manner, the drive motor assembly **124** is configured to regulate delivery of fluid by actuating the piston **144** (under the control of the electronics module and/or control system of the fluid infusion device **100**). As described above, if a stepper motor is employed, then the drive motor assembly **124** can regulate delivery of fluid from the fluid infusion device **100** in discrete actuation or delivery strokes. The fluid infusion device **100** can employ the sleeve **120** or an equivalent feature (such as an anti-rotation key) to inhibit rotation of the drive motor assembly **124**, which might otherwise result from torque generated by the motor **136**. In some embodiments, the drive shaft of the drive motor assembly **124**, the drive screw **125**, and the slide **121** are all coaxially centered within the longitudinal axis of travel of the piston **144**. In certain alternative embodiments, one or more of these components may be offset from the center of the axis of travel and yet remain aligned with the axis of travel, which extends along the length of the fluid reservoir **111**.

As mentioned above, certain embodiments of the fluid infusion device **100** accommodate removable and replaceable fluid reservoirs. When the slide **121** and, therefore, the piston **144** of the fluid reservoir **111** are in their fully extended positions, the piston **144** has forced most, if not all, of the fluid out of the fluid reservoir **111**. After the piston **144** has reached the end of its travel path, indicating that the fluid reservoir **111** has been depleted, the fluid reservoir **111** may be removed such that the female portion **146** of the piston **144** disengages from the coupler **142** of the slide **121**. After the empty (or otherwise used) fluid reservoir **111** is removed, the electronics module or control system of the fluid infusion device **100** initiates a rewind operation during which the motor **136** rotates in the reverse direction to rewind the slide **121** back to its fully retracted position. Thereafter, a new or refilled fluid reservoir **111** can be installed, seated, and primed for use. In this regard, an embodiment provides for advancement of the slide **121** upon the insertion of a fluid reservoir **111** into the housing **112**. The slide **121** advances until its coupler **142** comes into contact with the piston **144** of the fluid reservoir **111**. In alternative embodiments having a threaded piston engagement, the slide **121** advances until the threads of the coupler **142** engage the threads in the female portion **146** of the piston **144**. When the threads engage in this fashion, they need not do so by twisting. Rather, they may ratchet over one another. In operation, the force sensor **126** may be used to determine when the slide **121** contacts the piston **144**, when the coupler **142** is properly seated in the female portion **146**, and/or when the fluid reservoir **111** has been primed and is ready to deliver measured doses of fluid.

Although the illustrated embodiment employs a coaxial or inline drive system, alternative configurations could be utilized. For example, a drive system that uses a lead screw, a drive nut, and actuation arms (of the type described in U.S. Pat. No. 6,485,465) may be employed, with the force sensor **126** positioned in an appropriate location. In various embodiments, the drive train might include one or more lead screws, cams, ratchets, jacks, pulleys, pawls, clamps, gears, nuts, slides, bearings, levers, beams, stoppers, plungers, sliders, brackets, guides, bearings, supports, bellows, caps, diaphragms, bags, heaters, or the like. Moreover, although the illustrated embodiment employs a sensor positioned at the end of the fluid drive train, other arrangements could be deployed. For example, a sensor could be placed at or near the front end of the fluid drive train.

In particular embodiments, the force sensor **126** is used to detect when the slide **121** contacts the piston **144**. Thus, after the fluid reservoir **111** is placed into the fluid infusion device **100**, the motor **136** is activated to move the slide **121** toward the fluid reservoir **111** to engage the piston **144**. In this regard, when a shoulder region **150** (see FIG. **3**) of the slide **121** first contacts the piston **144**, the electronics module detects an increase in force imparted to the force sensor **126**. The measured force continues to increase as the motor **136** continues to drive forward, in response to the fluid resistance in the fluid reservoir **111**. When the slide **121** is properly seated with the piston **144**, the measured force increases to the seating threshold level. During the seating operation, if the measured force exceeds this seating threshold, the motor **136** is stopped until further commands are issued. The seating threshold is generally about 1.5 pounds. In alternative embodiments, higher or lower seating thresholds may be used depending on the force required to mate the slide **121** with the piston **144**, the force required to urge fluid from the fluid reservoir **111**, the speed of the motor **136**, the accuracy and resolution of the force sensor **126**, or the like.

It should be appreciated that other force thresholds can be used for other purposes. During priming of fluid reservoirs, for example, a threshold of about 4.0 pounds is used. In some embodiments, levels greater than about 5.0 pounds are used to detect shock loads that may be damaging to the fluid infusion device **100**.

The force sensor **126** is configured to react in response to force imparted thereto. In this regard, electrical, mechanical, magnetic, and/or other measurable or detectable characteristics of the force sensor **126** vary in accordance with the amount of force applied to the force sensor **126**. In practice, the force sensor **126** might implement or otherwise leverage known sensor technologies, such as the sensor technology described in U.S. Pat. No. 6,485,465. As shown in FIG. **2**, the force sensor **126** includes at least one electrical lead **154** that is electrically coupled to the electronics module (or controller) of the fluid infusion device **100**. Alternatively, the force sensor **126** could use wireless data communication technology to provide force-related data to the electronics module. In certain implementations, the force sensor **126** is suitably configured to indicate or generate a plurality of different output levels that can be monitored and/or determined by the electronics module. In practice, the output levels obtained from the force sensor **126** are initially conveyed as analog voltages or analog currents, and the electronics module includes an analog-to-digital converter that transforms a sampled analog voltage into a digital representation. Conversion of sensor voltage into the digital domain is desirable for ease of processing, comparison to threshold values, and the like.

In particular embodiments, the force sensor **126** is realized as an electromechanical component having at least one variable resistance that changes as the force applied to the force sensor **126** changes. In alternative embodiments, the force sensor **126** is a capacitive sensor, a piezoresistive sensor, a piezoelectric sensor, a magnetic sensor, an optical sensor, a potentiometer, a micro-machined sensor, a linear transducer, an encoder, a strain gauge, or the like, and the detectable parameter or characteristic might be compression, shear, tension, displacement, distance, rotation, torque, force, pressure, or the like. In practice, changing characteristics of the force sensor **126** are associated with output signal characteristics that are responsive to a physical parameter to be measured. Moreover, the range and resolution of the monitored output signal provides for the desired number of output levels (e.g., different states, values, quantities, signals, magnitudes, frequencies, steps, or the like) across the range of measurement. For example, the force sensor **126** might generate a low or zero value when the applied force is relatively low, a high or maximum value when the applied force is relatively high, and intermediate values when the applied force is within the detectable range.

In certain exemplary embodiments, the electronics module of the fluid infusion device **100** maintains a constant supply voltage across the force sensor **126**, and the monitored output signal of the force sensor **126** is a signal current that passes through a resistive material of the force sensor **126**. Thus, the signal current varies with the amount of force applied to the force sensor **126** because the resistance of the force sensor **126** varies with force and the supply voltage across the force sensor **126** is constant. The electronics module converts the monitored signal current into a signal voltage, which is then used as an indication of the force imparted to the force sensor **126** (which may be caused by the drive motor assembly **124**, by fluid pressure in the fluid reservoir **111**, by impact experienced by the fluid infusion device **100**, etc.). In alternative embodiments, a constant supply current is used and the signal voltage across the force sensor **126** varies with force (fluid pressure).

In certain embodiments, sensor measurements are taken prior to commanding the drive system to deliver fluid, and soon after the drive system has stopped delivering fluid. In alternative embodiments, sensor data is collected on a continuous basis at a particular sampling rate (for example, 10.0 Hz, 3.0 Hz, once every 10 seconds, once a minute, once every five minutes, or the like). In further alternative embodiments, the sensor data is only collected prior to commanding the drive system to deliver fluid. In still further alternative embodiments, sensor data is collected during fluid delivery (during delivery strokes and/or between delivery strokes).

In practice, the force sensor **126** and associated electronics are designed to measure forces between about zero pounds and about five pounds with a desired resolution of about 0.01 pounds. In preferred embodiments, the force sensor **126** and associated electronics provide a relatively linear voltage output in response to forces applied to the force sensor **126** by one or more drive train components. In alternative embodiments, the range and resolution of the force sensor **126** might vary from that specified above. Furthermore, the sensor range and/or resolution may vary in accordance with the concentration of the fluid being delivered, the diameter of the fluid reservoir **111**, the diameter of the fluid path, the nominal range of force experienced during normal operation of the drive motor assembly **124**, the amount of sensor noise, the algorithms applied to detect trends from sensor measurements, or the like. Moreover, the fluid infusion device **100** and the force sensor **126** should be suitably configured to survive shock levels that result in much higher forces being applied to the force sensor **126** than the intended sensor measurement range.

As mentioned previously, the fluid infusion device **100** is suitably configured to support a number of techniques, processes, and methodologies that utilize the force sensor **126**. In practice, the fluid infusion device **100** includes an electronics module, processing logic, software applications, and/or other features that are used to carry out the various operating processes described here. In this regard, FIG. **4** is a schematic block diagram representation of an embodiment of the fluid infusion device **100**. FIG. **4** depicts some previously-described elements of the fluid infusion device **100** as functional blocks or modules, namely, the display element **106**; the user interface **104**; the drive motor assembly **124**; and the force sensor **126**. FIG. **4** also depicts the fluid reservoir **111** and the infusion set **102** in block format. This particular embodiment of the fluid infusion device **100** also includes, without limitation: a suitable amount of memory **160**; an electronics module **162** (which may include or cooperate with one or more processors, processing modules, controllers, state machines, or the like); a power supply **164** such as a battery or a battery pack; and other infusion pump hardware, software, and applications **166**. The elements of the fluid infusion device **100** may be coupled together via an interconnection architecture **168** or arrangement that facilitates transfer of data, commands, power, etc.

The display element **106** represents the primary graphical interface of the fluid infusion device **100**. The display element **106** may leverage known plasma, liquid crystal display (LCD), thin film transistor (TFT), and/or other display technologies. The actual size, resolution, and operating specifications of the display element **106** can be selected to suit the needs of the particular application. Notably, the display element **106** may include or be realized as a touch screen display element that can accommodate touch screen techniques and technologies. In practice, the display element **106** may be driven by a suitable display driver to enable the fluid infusion device **100** to display physiological patient data, status information, clock information, alarms, alerts, and/or other information and data received or processed by the fluid infusion device **100**.

The user interface **104** may include a variety of items such as, without limitation: a keypad, keys, buttons, a keyboard, switches, knobs (which may be rotary or push/rotary), a touchpad, a microphone suitably adapted to receive voice commands, a joystick, a pointing device, an alphanumeric character entry device or touch element, a trackball, a motion sensor, a lever, a slider bar, a virtual writing tablet, or any device, component, or function that enables the user to select options, input information, or otherwise control the operation of the fluid infusion device **100**. In this context, the user interface **104** may cooperate with or include a touch screen display element **106**. The user interface **104** allows a user to control the delivery of fluid via the infusion set **102**.

The electronics module **162** may include or be implemented with a general purpose processor, a content addressable memory, a digital signal processor, an application specific integrated circuit, a field programmable gate array, any suitable programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination designed to perform the functions described here. A processor device may be realized as a microprocessor, a controller, a microcontroller, or a state machine. Moreover, a processor device may be implemented as a combination of computing devices, e.g., a combination of a digital signal processor and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a digital signal processor core, or any other such configuration.

The electronics module **162** may include one processor device or a plurality of cooperating processor devices. Moreover, a functional or logical module/component of the fluid infusion device **100** might be realized by, implemented with, and/or controlled by processing logic maintained by or included with the electronics module **162**. For example, the display element **106**, the user interface **104**, the drive motor assembly **124**, and/or the infusion pump hardware, software, and applications **166** (or portions thereof) may be implemented in or controlled by the electronics module **162**.

The memory **160** may be realized as RAM memory, flash memory, EPROM memory, EEPROM memory, registers, a hard disk, a removable disk, a CD-ROM, or any other form of storage medium known in the art. In this regard, the memory **160** can be coupled to the electronics module **162** such that the electronics module **162** can read information from, and write information to, the memory **160**. In the alternative, the memory **160** may be integral to the electronics module **162**. As an example, a processor of the electronics module **162** and the memory **160** may reside in an ASIC. In practice, a functional or logical module/component of the fluid infusion device **100** might be realized using program code that is maintained in the memory **160**. Moreover, the memory **160** can be used to store data utilized to support the operation of the fluid infusion device **100**, including, without limitation, sensor data, force measurements, force thresholds, alert/alarm history, and the like (as will become apparent from the following description).

The infusion pump hardware, software, and applications **166** are utilized to carry out fluid infusion features, operations, and functionality. Thus, the infusion pump hardware, software, and applications **166** may include or cooperate with the infusion set **102** and/or the fluid reservoir **111** (as described above). It should be appreciated that the infusion pump hardware, software, and applications **166** may leverage known techniques to carry out conventional infusion pump functions and operations, and such known aspects will not be described in detail here.

A fluid infusion device can support one or more features or operations that enhance its fluid infusion functionality and/or enhance the user experience of the fluid infusion device. The following sections include descriptions of various processes and methods that may be performed by a fluid infusion device. The various tasks performed in connection with a given process may be performed by software, hardware, firmware, or any combination thereof. For illustrative purposes, a process might be described with reference to elements mentioned above in connection with FIGS. **1**-**4**. In practice, portions of a given process may be performed by different elements of the described system, e.g., a sensor, a drive motor assembly, an electronics module, a processor, or the like. It should be appreciated that a described process may include any number of additional or alternative tasks, the tasks included in a particular flow chart need not be performed in the illustrated order, an embodiment of a described process may omit one or more of the illustrated tasks, and a given process may be incorporated into a more comprehensive procedure or process having additional functionality not described in detail herein.

Sensor Health Monitoring

For reasons presented above, the force sensor **126** in the fluid infusion device **100** is an important component that, at a minimum, is used to determine when a new fluid reservoir **111** is seated and when an occlusion has occurred. During use, the output and/or electromechanical characteristics of the force sensor **126** may drift over time. The drift can be attributed to the aging of mechanical components, impacts or shocks suffered by the fluid infusion device **100**, environmental exposure, etc. It is desirable to monitor sensor drift so that the fluid infusion device **100** can alert the patient if the sensor drift exceeds a tolerable amount. Notably, the force sensor **126** cannot be easily or conveniently calibrated, for example on a yearly basis, because it is not accessible. Consequently, the force sensor **126** should not divert from a calibration curve (which contemplates typical variations or drifting of the force sensor **126**) over the life of the product.

The sensor health monitoring features of the fluid infusion device **100** can be utilized to determine and monitor the drift characteristics of the force sensor **126**. In accordance with one approach, it is assumed that the force sensor **126** experiences a consistent and relatively low load during rewind operations, which are performed before installing a new fluid reservoir **111**. During a calibration routine (which may be performed, for example, during manufacturing of the fluid infusion device **100**), the device records force data collected during one or more rewind stages. The force data is used to generate a nominal rewind force value, which may represent an average of the collected values, the maximum collected value, the minimum collected value, or the like. This rewind force value is saved in the memory **160** of the fluid infusion device **100**. Thereafter, when deployed and operating, the fluid infusion device **100** performs a rewind force average check and compares the value to the saved rewind force. If the measured rewind force is within a specified range of the calibration rewind force value, then the fluid infusion device **100** continues to operate as usual. If, however, the measured rewind force drifts below a level that is not acceptable, then the fluid infusion device **100** can generate an alarm, an alert, or respond in a predetermined manner. The sensor health can be checked whenever a new fluid reservoir **111** is installed, typically every three days.

FIG. **5** is a flow chart that illustrates an embodiment of a process **200** associated with the operation of a fluid infusion device, such as the fluid infusion device **100** described above. The process **200** may begin with the activation of a rewind operation of the drive motor assembly (task **202**). As explained above, the drive motor assembly rewinds after removing an old fluid reservoir and before installing a new fluid reservoir. Accordingly, task **202** could be automatically performed whenever a fluid reservoir is removed from the fluid infusion device. As another option, task **202** could be performed (either automatically or initiated by the user) at other times when the fluid infusion device **100** is not delivering fluid. In this regard, the slide **121** can be retracted from the piston **144** while leaving the piston **144** in place. The position of the slide **121** prior to retraction can be stored such that the slide **121** can be precisely returned to its former position to continue delivering fluid. In response to the rewind activation, the process **200** rewinds the drive motor assembly by an appropriate amount (task **204**). To accommodate installation of a new fluid reservoir, task **204** rewinds the drive motor assembly until the slide is fully retracted.

The absence of a fluid reservoir during the rewind operation results in no loading on the drive motor assembly. For this reason, the process **200** determines a rewind force imparted to the force sensor during the rewind operation (task **206**). Task **206** could obtain a single rewind force measurement at any time during the rewind operation, it could calculate an average rewind force based upon any number of rewind force measurements obtained during the rewind operation, or it could generate any rewind force value or metric that is based upon one or more individual rewind force measurements obtained during the rewind operation. For simplicity, this particular embodiment of the process **200** assumes that a single rewind force measurement is determined at task **206**.

The process **200** may continue by comparing the rewind force measurement to one or more threshold forces. For this example, the process **200** determines whether or not the rewind force measurement falls within a predetermined range, and initiates corrective action at the fluid infusion device when the rewind force measurement does not fall within that range. Thus, if the rewind force measurement is less than the lower threshold force (query task **208**), then the fluid infusion device initiates and executes appropriate corrective action (task **210**). Similarly, if the rewind force measurement is greater than the upper threshold force (query task **212**), then the fluid infusion device initiates and executes appropriate corrective action (task **214**). The corrective action taken by the fluid infusion device may include one or more of the following, without limitation: generating an alert or an alarm at the fluid infusion device; stopping or inhibiting fluid delivery; presenting instructions, a maintenance reminder, or a message to the user; or the like. In practice, an alert, alarm, or warning may include, without limitation: sounds; one or more synthesized voices; vibrations or other haptic feedback; displayed symbols or messages; lights; transmitted signals; Braille output; or the like. Other forms of corrective action include, without limitation: running a self test of the fluid infusion device; recalibrating the threshold forces; temporarily disabling the fluid infusion device; or the like.

A rewind force measurement that is less than the lower threshold force indicates that the measured force is less than the actual force applied to the force sensor. Consequently, it may be more difficult for the fluid infusion device to accurately and quickly detect the onset of an occlusion in the fluid path based on the force sensor output. On the other hand, a rewind force measurement that is greater than the upper threshold force indicates that the measured force is greater than the actual force applied to the force sensor. Consequently, the fluid infusion device might detect the onset of an occlusion too soon, or falsely detect an occlusion. Therefore, the type of corrective action taken at task **210** may be different than the type of corrective action taken at task **214**. In this regard, different alert characteristics (colors, volume, frequency, sounds), different message content or formats, and/or different combinations of the corrective actions described above could be initiated and executed at tasks **210**, **214**.

It should be appreciated that the fluid infusion device processes the output levels associated with the force sensor to determine the current operating health of the force sensor. If the rewind force measurement falls within the specified range (i.e., it is greater than the lower threshold force and less than the upper threshold force), then the fluid infusion device can continue operating as usual. For example, the fluid infusion device can complete the rewind operation (task **216**, which may be performed before or during tasks **206**, **208**, **210**, **212**, **214**) before placement of a new fluid reservoir into the fluid infusion device. After the new fluid reservoir is installed, the process **200** activates a reservoir seating operation (task **218**) and uses the force sensor to detect when the new fluid reservoir is seated in the fluid infusion device. In this regard, the drive motor assembly is activated to advance the slide until a predetermined seating force has been detected (task **220**). After detection of this seating force, the drive motor assembly can be further advanced by an appropriate amount during a priming operation, which is activated to prepare the fluid infusion device and the new fluid reservoir for normal operation.

As mentioned above, a rewind operation and the related force measurements could be performed before the fluid reservoir needs to be replaced. If the process **200** determines that the force sensor is operating as expected during such a rewind operation, then task **218** and task **220** are performed to return the slide **121** to its former position in contact with the piston **144**. Thereafter, fluid delivery may continue as though the rewind operation never took place.

During normal use, the fluid infusion device regulates the delivery of fluid from the fluid reservoir by controlling the movement of the drive motor assembly (task **222**). The same force sensor used to determine the rewind force measurements can also be used to monitor for the onset of an occlusion (task **224**). In particular, the force imparted to the force sensor (which is indicative of the pressure in the fluid reservoir) is determined and analyzed in accordance with one or more occlusion detection schemes to detect an occlusion of the infusion set or elsewhere in the fluid delivery path.

In certain embodiments, the measured rewind forces (see task **206**) observed during operation are recorded in the memory of the device. The historical rewind force data may be used to detect trends and drifting in the measured rewind force, e.g., consistently decreasing, consistently increasing, random variation, or the like. Thus, even if a measured rewind force does not trigger corrective action, the rewind force values can be saved for diagnostic purposes, statistical evaluation of the device, and the like.

The preceding description of the process **200** illustrates how rewind force thresholds can be used to check the operating health of the force sensor. The threshold forces may be fixed or adaptive (to accommodate and compensate for drifting of the force sensor). In this regard, FIG. **6** is a flow chart that illustrates an embodiment of a rewind force calibration process **300** for a fluid infusion device, such as the fluid infusion device **100**. In certain scenarios, the process **300** is performed at least once during manufacturing of the fluid infusion device, and the calibrated threshold forces are stored as fixed values for the life of the device. In other situations, the process **300** could be performed periodically (e.g., at the request of the user, every year, or in accordance with a maintenance schedule). The illustrated embodiment of the process **300** begins by performing a calibrating rewind operation (task **302**). No fluid reservoir is present during calibration, and the drive motor assembly is controlled as necessary to execute a rewind operation.

During the calibrating rewind operation, the process **300** determines a calibration rewind force imparted to the force sensor (task **304**). Task **304** could obtain a single rewind force measurement at any time during the calibrating rewind operation, it could calculate an average calibration rewind force based upon any number of rewind force measurements obtained during the calibrating rewind operation, or it could generate any calibration rewind force value or metric that is based upon one or more individual calibration rewind force measurements obtained during the calibrating rewind operation. For simplicity, this particular embodiment of the process **300** assumes that a single calibration rewind force measurement is determined at task **304**. If the calibration period is finished (query task **306**), then the process **300** continues. If not, the process **300** performs another calibrating rewind operation and determines a respective calibration rewind force measurement for that operation. In other words, tasks **302**, **304**, **306** can be repeated any desired number of times, resulting in a plurality of calibration rewind forces that can be saved for subsequent analysis and processing.

Upon completion of the calibration period, the process **300** calculates a nominal rewind force from the plurality of calibration rewind forces (task **308**). The nominal rewind force can be determined using any desired formula, algorithm, relationship, or equation. For the simple implementation described here, the nominal rewind force is calculated as an average of the plurality of calibration rewind forces. As mentioned previously, the nominal rewind force is ideally equal or equivalent to a load of zero pounds on the drive motor assembly. Accordingly, an acceptable nominal rewind force will typically be within the range of about −0.50 to +0.50 pounds (this range is merely exemplary, and an embodiment could utilize different upper and/or lower values). In this regard, the process **300** might check the calculated nominal rewind force to ensure that it falls within a predetermined range of acceptable values. Thus, if the nominal rewind force falls outside of that range, the process **300** could generate an alarm, an alert, or a warning for the user, and/or repeat the portion of the calibration routine associated with tasks **302**, **304**, **306**, and **308**.

Assuming that the calculated nominal rewind force is acceptable, it can be stored in a memory element of the fluid infusion device (task **310**) for future reference if needed. For this particular embodiment, the process **300** derives the lower threshold rewind force and the upper threshold rewind force from the calculated nominal rewind force (task **312**). For example, the lower threshold force might be calculated by subtracting a designated amount from the nominal rewind force, and the upper threshold force might be calculated by adding a designated amount to the nominal rewind force. Moreover, the manner in which these threshold forces are calculated could vary as a function of the nominal rewind force itself. For instance, one threshold calculation scheme could be used when the nominal rewind force is greater than zero, and a different threshold calculation scheme could be used when the nominal rewind force is less than zero. After the rewind force thresholds have been derived, they can be stored in a memory element of the fluid infusion device (task **314**) for subsequent use as needed, e.g., during execution of the process **200**. In practice, these rewind force thresholds can be saved as fixed values that do not change during the operating life of the fluid infusion device. In this manner, the process **300** results in a specified range of rewind forces that is indicative of a healthy operating status of the force sensor.

In accordance with another approach, the operating health of the force sensor **126** is checked more frequently, namely, at times other than during a rewind operation. This alternate approach (which may be utilized in conjunction with the first approach described above) checks the health of the force sensor in an ongoing manner without having to wait until a rewind operation. More particularly, this technique checks the measured or detected force associated with the drive motor assembly at designated motor pulses (e.g., at every motor pulse). If the measured force is below a predetermined value, the fluid infusion device will take corrective action because this condition indicates that the force sensor has drifted beyond its limit in the negative direction. If the measured force is above a predetermined value, then the fluid infusion device assumes that the force sensor has drifted in the positive direction, which might result in false or early detection of an occlusion.

FIG. **7** is a flow chart that illustrates another embodiment of a process **400** associated with the operation of a fluid infusion device, such as the fluid infusion device **100** described above. The process **400** may begin any time after activating a fluid delivery operation of the fluid infusion device (task **402**). During a fluid delivery operation, the drive motor assembly is used to actuate the fluid reservoir in a controlled manner. In certain implementations, fluid delivery operations are carried out in a stepwise manner such that fluid is administered in discrete fluid delivery strokes (or pulses) of the slide. In practice, a fluid delivery operation may involve multiple fluid delivery strokes; the exact number will depend on the desired amount of fluid to be delivered. Accordingly, the process **400** continues by performing the next fluid delivery action, pulse, or stroke with the drive motor assembly (task **404**), and determining and saving the corresponding measure of actuation force imparted to the force sensor during that fluid delivery action (task **406**).

Next, the process **400** compares the measure of actuation force to a range of valid values for the fluid infusion device (task **408**). In practice, there will be a range of force sensor outputs or readings that correspond to or otherwise represent normally expected measures of actuation forces. For example, if the force sensor is operating as expected, then it might have a limited and predetermined analog output range, which in turn corresponds to a limited and predetermined range of encoded digital values. If, however, the force sensor is damaged, is beginning to fail, or is otherwise operating in an unexpected or unusual manner, then the resulting analog output and encoded digital values could be outside of the normally expected range. Measured values of actuation force that are outside of the normally expected range are therefore treated as invalid or undefined measures.

If the current measure of actuation force is not invalid as defined by the particular settings and configuration of the fluid infusion device (query task **410**), then the process **400** may return to task **404** to perform the next fluid delivery action. This enables the fluid infusion device to monitor the operating integrity of the force sensor during fluid delivery and in an ongoing and dynamic manner. If, however, the current measure of actuation force is outside the range of valid values, then the process may generate a flag or otherwise record an invalid force event for the current measure of actuation force (task **412**). The recorded event may include information such as, for example, the delivery time of the current stroke, the current measure of actuation force, the current position of the slide or drive motor, or the like. Data associated with the recorded event can be saved for subsequent analysis, for reporting purposes, for troubleshooting or diagnostic purposes, etc. For instance, this embodiment of the process **400** continues by analyzing a set of invalid force events to determine a course of action for the fluid infusion device (task **414**). In this regard, the set of invalid force events may represent a designated number of past invalid force events, including the current invalid force event, collected over a particular period of time, collected for a designated number of delivery strokes, or the like. In certain situations, the set of invalid force events may correspond to only one event, which could be sufficient to trigger an alarm or an alert if deemed necessary. This allows the process **400** to initiate corrective action based on a single actuation stroke or pulse, based on an average measure of multiple pulses, based on detected patterns of measured forces, or the like. Task **414** may be performed to reduce the likelihood of false alerts or false alarms associated with the operating health of the force sensor. In this regard, the process **400** may be used to detect a positive drift and/or a negative drift in the force sensor, which may result in the lack of timely alerts. Thus, the detection of only one invalid force event during an extended period of time or over the course of many delivery strokes can be disregarded without triggering an alert.

The process **400** could utilize any type of criteria that influences whether or not a single invalid force event or a set of invalid force events will cause the fluid infusion device to respond. For example, the criteria may dictate that at least a threshold number of invalid force events corresponding to consecutive fluid delivery actions must be recorded before a user alert is generated. As another example, the criteria may dictate that at least a threshold number of invalid force events must be recorded within a designated period of time (such as 60 minutes) before any corrective action is taken. The criteria may be chosen such that transient conditions that might influence the operation of the force sensor (e.g., handling of the device, bumping or dropping the device, driving over a pothole, etc.) do not trigger an alarm. Rather, the criteria may be selected such that the fluid infusion device is given the opportunity to recover and settle from such transient events.

Accordingly, if certain designated criteria is satisfied (query task **416**), then the process **400** can initiate and execute appropriate corrective action at the fluid infusion device (task

418). If the criteria has not been satisfied, then the process **400** may return to task **404** to perform the next fluid delivery action. Thus, some form of corrective or remedial action can be taken in response to the recording of one or more invalid force events, where the recorded events are indicative of poor operating health of the force sensor. Task **418** may initiate and execute any of the corrective actions described above for tasks **210** and **214** of the process **200**.

The process **400** represents a simplified embodiment that analyzes actuation forces and checks for valid measures of actuation force from one delivery stroke or pulse of the drive motor assembly to another. Alternative embodiments, however, could implement a more complex scheme that calculates and considers any suitable parameter, measure of force, force-related metric, or the like. For example, rather than compare the actuation forces to a range of valid measures per se, the fluid infusion device could instead calculate any appropriate parameter from the measured actuation force, where the parameter is somehow indicative of the operating health of the force sensor, and then compare the value of that parameter to certain predetermined performance criterion for the force sensor. If the parameter does not satisfy the performance criterion, then the fluid infusion device can take corrective or remedial action.

In some embodiments, the fluid infusion device **100** is suitably configured to check the operating condition of the force sensor **126** using a known and calibrated force applied to the force sensor **126**. Although not always required, this example assumes that the force sensor **126** is tested after removing the fluid reservoir **111** and during a time when fluid need not be dispensed. Imparting a known nonzero calibration force to the force sensor **126** can be accomplished using any suitable component, device, fixture, or equipment. In accordance with one exemplary embodiment, the fitting **110** is replaced with a calibration fitting that is provided with a precisely calibrated spring or other element that provides a known force at a specified amount of deflection. After installing the calibration fitting, the slide **121** is advanced by a designated amount, which can be controlled by monitoring encoder counts or other metrics related to the operation of the drive motor **136**. When the slide **121** has advanced by the designated amount, the force element (e.g., the spring) is expected to impart the calibrating force to the slide **121**, which in turn imparts the calibrating force to the force sensor **126**.

When the slide **121** has reached the calibration position, the corresponding measure of actuation force is recorded and compared to a value associated with the expected calibrating force. If the recorded value is different than the expected calibration value by more than a stated amount, then the fluid infusion device **100** (and/or the user) can assume that the force sensor **126** is defective or otherwise not functioning according to specification. It should be appreciated that the calibration force should fall within the normal measuring range of the force sensor **126**.

Reservoir Seating (Presence) Monitoring

The force sensor **126** in the fluid infusion device **100** may also be utilized to monitor the presence and seating status of the fluid reservoir **111**. In this regard, the electronics module **162** of the fluid infusion device **100** can be utilized to process the output levels of the force sensor **126** to determine the seating status of the fluid reservoir **111** in the reservoir cavity **134** in an ongoing manner. The fluid infusion device **100** can alert the user when the fluid reservoir **111** has been accidentally removed or inadvertently dislodged. The fitting **110** might be inadvertently rotated or loosened during physical activity (e.g., while the user is playing a sport or exercising), which in turn might result in removal or dislodging of the fluid reservoir **111**. When this happens, proper coupling between the piston **144** of the fluid reservoir **111** and the coupler **142** of the slide **121** could be lost. For safe measure, the fluid infusion device **100** notifies the user shortly after the fluid reservoir **111** is partially removed, completely removed, or dislodged by more than a predetermined amount.

The fluid infusion device **100** uses the force sensor **126** to determine the seating status of the fluid reservoir **111**. Accordingly, no additional components, sensors, or assembly time is needed to implement this feature. In certain embodiments, the fluid infusion device **100** uses a scheme that adaptively tracks the forces of delivery strokes. The fluid infusion device **100** records the force of a delivery stroke. If the measured force remains the same or increases from stroke-to-stroke, then the fluid infusion device **100** assumes that a fluid reservoir is in place and is properly seated. Moreover, slight variations in the detected force can be disregarded to contemplate normal and expected force variations that typically occur along the travel path of a fluid reservoir. However, a characterized drop in force that is greater than a certain amount indicates that (1) the fluid reservoir **111** has been removed or dislodged or (2) the fluid infusion device **100** may have been dropped or bumped, temporarily disturbing the force sensor **126**. For the second scenario, design engineers can characterize how many pulses (delivery strokes) and/or how much time is typically needed to allow the fluid infusion device **100** to recover from a disturbing impact or force, assuming that the fluid reservoir **111** remains present and properly seated. If the measured force does not return to a nominal value after a designated number of strokes or a predetermined amount of time, the fluid infusion device **100** can conclude that the fluid reservoir **111** has been removed or disturbed and, in turn, generate an alert or a warning message for the user.

Notably, the reservoir presence scheme is adaptive in nature, and it takes into account variations such as sensor drift, reservoir frictional force variation, and minor shocks. The reservoir presence methodology actively monitors for an ongoing drop in force greater than a set value. This approach is desirable because it accommodates variations (such as sensor drift) that might be introduced over the life of the fluid infusion device **100**, variations from one reservoir to another, and variations (such as fluid pressure) that might occur during use of a single reservoir. For example, if frictional force increases due to reservoir dynamics, the fluid infusion device **100** will adapt and set the increased force measure as a new baseline value. Similarly, if the frictional force is decreasing due to reservoir dynamics, the fluid infusion device **100** will adapt the lower force measure as the new baseline value (as long as the rate of decrease and/or the force variation is less than a specified amount). This feature accommodates variation in frictional force without false alarms. Accordingly, the fluid infusion device **100** adaptively resets the baseline force value as long as the rates of change are within normal limits.

FIG. **8** is a flow chart that illustrates an embodiment of a process **500** that checks the seating status of a fluid reservoir of a fluid infusion device, such as the fluid infusion device **100** described above. The process **500** employs a simple force threshold for purposes of determining the seating status of the fluid reservoir. In this regard, the process **500** may begin by obtaining, calculating, or accessing the force threshold (task **502**), which represents an amount of force that is indicative of a dislodged, removed, displaced, or otherwise unseated state of the fluid reservoir. The force threshold may be adaptively updated in response to certain operating conditions, it may be one of a plurality of different available threshold values, it may be a predetermined and fixed value, or the like. For this example, the force threshold is a pre-stored value that is fixed during the operating lifespan of the fluid infusion device. In other embodiments (described below), the force threshold can be calculated in a dynamic manner to contemplate typical variations such as drifting of the force sensor.

Under typical operating conditions for exemplary embodiments, the normally expected force imparted to the force sensor when the fluid reservoir is properly seated is less than about 1.5 pounds. Moreover, under typical operating conditions for exemplary embodiments, the normally expected actuation force imparted to the force sensor during a fluid delivery stroke is less than about 1.5 pounds. In certain implementations, the force threshold used by the process **500** is calculated as a function of the nominal seating force and/or as a function of the nominal actuation force, and the force threshold is stored in a memory element of the fluid infusion device. For example, the force threshold might be calculated to be less than the average fluid delivery actuation force by a given amount, such as a percentage of the average fluid delivery actuation force. As another example, the force threshold is calculated such that it is a predefined amount of force less than the nominal expected actuation force. In practice, regardless of the manner in which it is calculated, the force threshold will typically be less than about 0.5 pounds.

In practice, the process **500** can be initiated whenever a fluid reservoir is installed into the fluid infusion device. Accordingly, the process **500** may confirm the initial seating of the fluid reservoir in the reservoir cavity (task **504**). Task **504** may additionally (or alternatively) confirm when the fluid infusion device has performed a priming operation, which typically occurs after installation of a fluid reservoir. After confirming that the fluid reservoir has been properly seated and/or otherwise properly installed, the fluid infusion device will eventually activate a fluid delivery operation, which in turn actuates the fluid reservoir with the drive motor assembly (task **506**). As described in more detail above, actuation of the fluid reservoir causes an amount of force to be imparted to the force sensor. Accordingly, the process **500** determines a measure of actuation force imparted to the force sensor during the fluid delivery operation (task **508**). Task **508** could obtain a single actuation force measurement at any time during the fluid delivery operation, it could calculate an average actuation force based upon any number of actuation force measurements obtained during the fluid delivery operation (e.g., a plurality of actuation forces corresponding to a plurality of consecutive delivery strokes), or it could generate any actuation force value or metric that is based upon one or more individual actuation force measurements obtained during the fluid delivery operation. For simplicity, this particular embodiment of the process **500** assumes that a single actuation force measurement is determined at task **508**. For this example, task **508** determines the measure of actuation force during the fluid delivery stroke itself. Alternatively (or additionally), task **508** could determine the measure of actuation force between fluid delivery strokes, and/or after a final fluid delivery stroke.

The process **500** may continue by comparing the actuation force measurement to one or more threshold forces. For this example, the process **500** compares the measure of actuation force to an amount of force (i.e., the force threshold obtained at task **502**) that is less than the normally expected actuation forces of the fluid infusion device. Accordingly, the process **500** checks whether or not the measure of actuation force (F_A) is less than the force threshold (F_T) at query task **510**. If the measure of actuation force is not less than the force threshold, then the process **500** assumes that the fluid reservoir is still in place and remains properly seated. Accordingly, the process **500** returns to task **506** to continue monitoring actuation force for the current fluid delivery operation (and for subsequent fluid delivery operations). If, however, query task **510** determines that the measure of actuation force is less than the force threshold and, therefore, that the measure of actuation force is indicative of an unseated state, then the fluid infusion device initiates and executes appropriate corrective action (task **512**). The corrective action taken by the fluid infusion device may include, without limitation, one or more of the actions described above for the process **200** (see FIG. **5**). It should be appreciated that the process **500** may consider any number of events (i.e., determinations that the measure of actuation force is less than the force threshold) and analyze a set of events to determine whether or not to initiate the corrective action. In this regard, the process **500** may determine whether a set of events satisfies certain predetermined criteria before taking corrective action, as described above with reference to tasks **412**, **414**, and **416** of the process **400**.

The process **500** is one exemplary embodiment that utilizes a fixed force threshold value to determine whether or not the fluid reservoir is seated. In contrast, FIG. **9** is a flow chart that illustrates another embodiment of a process **600** that employs an adaptive scheme for checking the seating status of the fluid reservoir. The process **600** can be performed whenever a fluid reservoir is installed into the fluid infusion device. Thus, the process **600** may begin by confirming the initial seating and priming of the fluid reservoir (task **602**), and activating a fluid delivery operation (task **604**), as described above for the process **500**. After initial seating of the fluid reservoir, the process obtains a baseline actuation force imparted to the force sensor (task **606**). The baseline actuation force may correspond to a measure of actuation force that is obtained during the priming operation or shortly thereafter, or it may correspond to a measure of actuation force that is obtained during the first fluid delivery operation for a new fluid reservoir. The process **600** assumes that the baseline actuation force is measured while the fluid reservoir is properly seated. Accordingly, the baseline actuation force can be stored in a memory element of the fluid infusion device for later use.

Eventually, the process **600** determines a measured actuation force imparted to the force sensor, where the measured actuation force corresponds to a designated delivery stroke of the drive motor assembly (task **608**). Task **608** could obtain a single actuation force measurement at any time during the fluid delivery operation, it could calculate an average actuation force based upon any number of actuation force measurements obtained during the fluid delivery operation (e.g., a plurality of actuation forces corresponding to a plurality of consecutive delivery strokes), or it could generate any actuation force value or metric that is based upon one or more individual actuation force measurements obtained during the fluid delivery operation. For simplicity, this particular embodiment of the process **600** assumes that a single actuation force measurement is determined at task **608**. As mentioned previously, the actuation force could be determined during the fluid delivery stroke itself, between fluid delivery strokes, or after a final fluid delivery stroke.

The process **600** may continue by comparing the actuation force measurement to a measure of force that is influenced by the baseline actuation force (F_B). For this example, the process **600** checks (query task **610**) whether the measured actuation force (F_A) is less than the baseline actuation force by some predetermined amount (F_T), which may be a fixed, adaptive, or dynamic threshold, as explained above for the process **500**. In other words, query task **610** determines whether $F_A<F_B-F_T$. If query task **610** determines that the

measure of actuation force is indicative of an unseated or dislodged fluid reservoir, then the fluid infusion device initiates and executes appropriate corrective action (task **612**), e.g., generates an alert or some indicia of an unseated fluid reservoir. Alternatively or additionally, the corrective action taken by the fluid infusion device may include, without limitation, one or more of the actions described above for the process **200** (see FIG. **5**). It should be appreciated that the process **600** may consider any number of events (i.e., individual determinations that $F_A<F_R-F_T$) and analyze a set of events to determine whether or not to initiate the corrective action. In this regard, the process **600** may determine whether a set of events satisfies certain predetermined criteria before performing task **612** (see the above description of tasks **412**, **414**, and **416** of the process **400**).

If the measure of actuation force is indicative of a properly seated fluid reservoir, then the process **600** updates the baseline actuation force as a function of the measured actuation force (task **614**). For this particular embodiment, task **614** updates the baseline actuation force by saving the measured actuation force for use as the next baseline actuation force. In practice, the fluid infusion device could implement a maximum and/or a minimum allowable baseline actuation force to ensure that the process **600** maintains a realistic baseline value. If for some reason the measured actuation force falls outside of the stated range of baseline force values, the fluid infusion device could generate an alert or take appropriate action. In this regard, a maximum or minimum value could serve as a confirmation or check of the operating health of the force sensor (see the Sensor Health Monitoring section of this description). Referring back to task **614**, after updating the baseline actuation force, the process **600** returns to task **708** to continue monitoring actuation force for the current fluid delivery operation (and for subsequent fluid delivery operations). Thus, the baseline actuation force is adjusted and updated in an ongoing manner while the process **600** monitors the seating status of the fluid reservoir. This adaptive approach enables the process **600** to consider and compensate for slight variations in measured actuation forces.

FIG. **10** is a flow chart that illustrates yet another embodiment of a process **700** that checks the seating status of a fluid reservoir. The process **700** uses a threshold force value that corresponds to the maximum expected variation in actuation force for the fluid reservoir. This threshold force value may be empirically determined, calculated based on known operating parameters of the fluid infusion device, or generated and dynamically updated during operation of the fluid infusion device. In certain embodiments, the threshold force value is determined and stored as a fixed value during the operating lifespan of the fluid infusion device. For example, and without limitation, the typical fluid delivery force for a fluid reservoir might be about 1.4 pounds between initial piston seating and depletion of the fluid reservoir, and the threshold force value might be about 0.2 pounds.

The process **700** obtains the measures of actuation force imparted to the force sensor for consecutive fluid delivery pulses (in practice, a measure of actuation force is recorded for each fluid delivery pulse). The process **700** calculates a pulse-to-pulse difference between consecutive fluid delivery pulses, where the pulse-to-pulse difference is based on respective measures of actuation force for the consecutive fluid delivery pulses. If the pulse-to-pulse difference is greater than the designated threshold force value, then the fluid infusion device initiates corrective action in some manner. In other words, if the difference in actuation force between the last fluid delivery pulse and the current fluid delivery pulse is more than the normally expected force variation, then the fluid infusion device assumes that the detected condition is indicative of a dislodged or removed fluid reservoir, or a transient state caused by an impact or sudden acceleration to the fluid infusion device. Note that in order to assume a removed or dislodged reservoir, the difference in force from one pulse to the next must be negative, i.e., the measured force has decreased rather than increased.

The process **700** may include some tasks that are similar or identical to counterpart tasks found in the process **600**, and such tasks will not be redundantly described here. The process **700** assumes that the fluid reservoir has already been properly seated for fluid delivery. This embodiment of the process **700** begins by initializing and maintaining a count (task **702**) that is indicative of the seating status of the fluid reservoir. The count may be initialized at any suitable value, although this example assumes that the count is initialized at a value of zero. The process **700** also sets the value of PULSE**1** to "True" (task **702**). The value of PULSE**1** is True only for the first actuation pulse following installation of a fluid reservoir. For all subsequent delivery pulses, the value of PULSE**1** is False. The fluid infusion device is primed (task **704**) such that fluid is introduced into the fluid pathway and through the infusion set tubing. During priming, the force imparted to the force sensor typically spikes (to about 1.4 pounds) when the slide initially contacts the plunger of the reservoir. After priming, however, the force decays and settles to a lower value (typically around 0.5 pounds).

The process **700** activates a fluid delivery operation (task **706**) to actuate the fluid reservoir, and performs the next fluid delivery action, stroke, or pulse (task **708**). As explained in more detail below, tasks **706** and **708** are usually performed after the priming operation is complete and after the force has settled to its nominal value (of about 0.5 pounds). If, however, the user commands a fluid delivery operation prematurely while the force is still decaying, then the force imparted to the force sensor at that time may be above the nominal value. The process **700** contemplates this scenario, as described below.

The process **700** continues by determining or obtaining a current measure of actuation force imparted to the force sensor for the current fluid delivery pulse (task **710**), as described previously. The current measure of actuation force (F) is recorded or saved in an appropriate manner. If PULSE**1** is True (query task **712**), meaning that the pulse actuated at task **708** is the first pulse for the installed reservoir, then the process **700** continues by setting the value of PULSE**1** to "False" (task **714**), and by comparing the current measure of actuation force (F) to a reference upper threshold force value that applies to initial pulses (RUT**1**), as indicated by query task **716**. The value of RUT**1** is selected to account for situations where the initial pulse is commanded prematurely, i.e., before the force has settled to its nominal value after priming. In other words, RUT**1** is selected to contemplate the possibility of unusually high force measurements associated with the first pulse commanded for a newly installed reservoir. For this particular example (where the normally expected nominal actuation force for the fluid reservoir is about 0.4 pounds), the value of RUT**1** may be chosen to be about 0.5 pounds, without limitation.

If the current measure of actuation force is less than RUT**1** (query task **716**), then the process **700** stores the current measure of actuation force (task **718**) for use as an adaptive reference force value (F_R), which is used for comparison purposes against subsequent force measurements. Execution of task **718** indicates that the actuation force associated with the initial delivery pulse does not represent a force measured shortly after priming, while the fluid in the delivery path is still settling to its nominal state. On the other hand, if the current measure of actuation force (F) is not less than RUT**1** (query task **716**), then the process **700** stores the value of RUT**1** as the current value of F_R (task **720**). Execution of task **720** indicates that the actuation force associated with the initial delivery pulse may have been sampled during a time when the fluid in the delivery path is still settling and, therefore, the measured force is still decaying from the relatively high value (e.g., about 1.4 pounds). Consequently, under this scenario the process **700** uses RUT**1** as the current adaptive reference force value.

After the value of F_R has been set (task **718** or task **720**), the process **700** waits for the next fluid delivery pulse (task **722**). When it is time to perform the next fluid delivery pulse, the process **700** returns to task **708** and continues as described above. In contrast to that described above, however, the value of PULSE**1** is False for the second and all further delivery pulses. Referring again to query task **712**, if PULSE**1** is not True (i.e., PULSE**1**=False), then the process **700** may continue by comparing the current measure of actuation force to the difference between the adaptive reference force value (F_R) and a threshold force value (query task **724**). For this example, the adaptive reference force value (F_R) may correspond to a past measure of actuation force that was recorded for a previous fluid delivery pulse, or it may correspond to RUT**1**, as described above. In particular embodiments, F_R might represent the measure of actuation force for the immediately preceding fluid delivery pulse (indeed, under normal operating conditions where the fluid reservoir remains properly seated, F_R will be adaptively updated to reflect the most recent measure of actuation force). In other words, the previous fluid delivery pulse associated with F_R and the current fluid delivery pulse will typically be consecutive fluid delivery pulses. Thus, the process **700** stores, maintains, and updates the adaptive reference force value as needed during operation of the fluid delivery device.

In practice, the process **700** might generate or store an initial value of F_R whenever a new fluid reservoir is installed, at the beginning of a fluid delivery operation, at designated times, at the request of the user, or at other appropriate times. This example assumes that F_R is initialized as described above in response to the first fluid delivery pulse of a fluid delivery operation. Thus, under typical and normal operating conditions the first measure of actuation force will be used as F_R for the immediately following fluid delivery pulse. If, however, the first measure of actuation force exceeds the initial upper threshold value, then the initial upper threshold value RUT**1** will instead be used as F_R for the next fluid delivery pulse.

Referring again to query task **724**, if the current measure of actuation force (F) is not less than the difference between the adaptive reference force value (F_R) and the threshold force value (F_T), then the process **700** assumes that the fluid reservoir remains properly seated. Accordingly, the process **700** resets the count to its initial value, e.g., zero (task **726**). The illustrated embodiment of the process **700** continues by comparing the current measure of actuation force (F) to an upper threshold force value (RUT), as indicated by query task **728**. This upper threshold value is selected such that it is indicative of the expected maximum actuation force for the fluid reservoir. For this particular example (where the normally expected actuation force for the fluid reservoir is about 1.4 pounds), the upper threshold force value may be chosen to be about 1.8 pounds, without limitation. If the current measure of actuation force is less than the upper threshold force value, the process **700** stores the current measure of actuation force for use as F_R with the next iteration (task **730**). In this regard, F_R can be adaptively and dynamically updated in an ongoing manner during the fluid delivery operation. After updating F_R, the process **700** waits until it is time to perform the next fluid delivery pulse (task **722**). Referring back to query task **728**, if the current measure of actuation force is not less than the upper threshold force value, then the process **700** leaves F_R unchanged and waits for the next fluid delivery pulse (task **722**). In other words, the previous value of F_R is retained for the next processing iteration. When it is time to perform the next fluid delivery pulse, the process **700** returns to task **708** and continues as described above.

Referring again to query task **724**, if $F<F_R-F_T$, then the process **700** initiates some form of corrective action, which is triggered by the detection of an abnormal or unexpected measure of actuation force. In this regard, the process **700** may place the fluid infusion device into a flagged state, perform additional checks, and/or perform additional data analysis to determine whether or not to execute corrective action, issue an alert, sound an alarm, generate a user message, etc. This particular example continues by obtaining one or more additional force readings (task **732**) and calculating an average measure of actuation force (F_{AVE}) based on the additional force readings. In practice, F_{AVE} may be calculated from the current measure of actuation force and any or all of the additional force readings. In certain embodiments, task **732** collects four additional force readings, and F_{AVE} is calculated as a weighted average of the current measure of actuation force and the four repeated measures of actuation force imparted to the force sensor.

Although the process **700** could use the current measure of actuation force itself as a trigger value, the illustrated embodiment instead uses F_{AVE} as the trigger value. In other words, the process **700** checks whether $F_{AVE}<F_R-F_T$ (query task **734**). If F_{AVE} is not less than the difference between the adaptive reference force value (F_R) and the threshold force value (F_T), then the process **700** assumes that the fluid reservoir remains properly seated, resets the count to its initial value (task **726**), and continues from task **726** as described above. If, however, $F_{AVE}<F_R-F_T$, then the process **700** changes the count by a designated amount to obtain an updated count (task **736**). Depending upon the embodiment and the initial count value, task **736** may increase or decrease the count. In certain embodiments, task **736** changes the count by an amount that is influenced or dictated by a volume of fluid to be delivered by a subsequent fluid delivery pulse, e.g., the next fluid delivery pulse. Alternatively, task **736** might change the count by an amount that is influenced or dictated by a volume of fluid delivered by the current fluid delivery pulse, or by a previous fluid delivery pulse. In accordance with one non-limiting example, task **736** increases the count by one when the next fluid delivery pulse corresponds to a relatively low volume of fluid (e.g., 0.025 units), increases the count by two when the next fluid delivery pulse corresponds to a relatively intermediate volume of fluid (e.g., 0.050 units), and increases the count by six when the next fluid delivery pulse corresponds to a relatively high volume of fluid (e.g., 0.200 units).

The above methodology for task **736** accounts for "slack" that is created in the drive system when the fluid infusion device is dropped or when the reservoir is dislodged. For example, assume that the slack represents a separation between the plunger of the reservoir and the tip of the actuating slide, and assume that it takes six pulses (each corresponding to a delivery of 0.025 Units), equivalent to 0.15 Units, to remove the slack. Therefore, the counter limit or threshold will be set to six. If after six "counts" the slack is not removed, i.e., the force is still low, the process **700** will trigger an alarm. If the device delivers fluid in 0.025 Unit pulses, it will take six pulses and, therefore, the count is incremented by one. On the other hand, if the fluid delivery is in 0.05 Unit increments, then the counter is incremented by two; if the fluid delivery is in 0.2 Unit pulses, the counter increments by six. Accordingly, the limit or threshold is met after six 0.025 Unit pulses, after three 0.05 Unit pulses, or after only one 0.2 Unit pulse. This allows the fluid infusion device to deliver various pulses and increment correctly.

After obtaining the updated count, the process **700** checks whether the updated count satisfies certain predetermined alert criteria (query task **738**). The alert criteria for the illustrated embodiment is simply a threshold count value or a limit, such as twelve or any appropriate number. Thus, if the updated count is greater than the limit, then the process **700** assumes that the fluid reservoir has been dislodged, loosened, or unseated. Consequently, the process **700** initiates and executes appropriate corrective action (task **740**), e.g., generates a seating status alert or some indicia of an unseated fluid reservoir. Alternatively or additionally, the corrective action taken by the fluid infusion device may include, without limitation, one or more of the actions described above for the process **200** (see FIG. **5**). If, however, query task **738** determines that the updated count does not satisfy the stated alert criteria, then the process **700** does not actually implement or execute any corrective action at this time. Rather, the process **700** may lead back to task **722** to wait for the next fluid delivery pulse, as described above. Notably, corrective action is executed by the illustrated embodiment of the process **700** only when the count exceeds the threshold limit. Moreover, the manner in which the count is reset by the process **700** ensures that unexpectedly low actuation force readings must be recorded for consecutive fluid delivery pulses before the fluid delivery device actually issues a warning or an alert. These aspects of the process **700** reduce nuisance alerts and allow the fluid infusion device to recover from transient conditions that might cause a temporary drop in the measured actuation force (e.g., dropping or bumping the fluid infusion device, mishandling the fluid infusion device, or the like). In certain embodiments, if at any point when the force is low and the count is being updated the force increases (i.e., the slide contacts the plunger of the reservoir), the counter is again reset to zero.

FIG. **11** is a graph that illustrates measures of actuation forces for a properly seated fluid reservoir. The plot **800** represents actuation force versus time (or, equivalently, fluid delivery pulses). The initial portion **802** of the plot **800** corresponds to the seating of the fluid reservoir. In practice, the device stops the seating process when a force of about 1.4 pounds is reached. Momentum of the motor results in some additional actuation, resulting in a peak of about 1.8 pounds. After seating and priming, however, the nominal force typically settles to about 0.5 pounds. Accordingly, the label P_1 represents the first fluid delivery pulse following the seating/priming procedure. The dashed line **804** schematically represents the threshold force value corresponding to the allowable drop in actuation force over any two consecutive fluid delivery pulses. Notably, even though the plot **800** fluctuates somewhat, the actuation force values do not violate the limit defined by the threshold force value. In other words, the plot **800** is indicative of a properly seated fluid reservoir under normal and expected operating conditions.

In contrast, FIG. **12** is a graph that illustrates measures of actuation forces for a fluid reservoir that becomes unseated. The plot **850** begins at a point after initial seating of the fluid reservoir. The initial segment **852** of the plot **850** is indicative of a properly seated fluid reservoir (assuming that the threshold force value is 0.15 pounds). The plot **850** experiences a temporary drop **854** that spans two fluid delivery pulses. For this example, the temporary drop **854** would trigger the counting mechanism described above with reference to the process **700**. However, the plot **850** recovers after the temporary drop **854** and, therefore, the count would be reset and no alert would be generated. At the fluid delivery pulse **856**, the plot **850** exhibits a significant and "permanent" drop. At this point, the counting mechanism would be activated. Notably, the drop in measured actuation force does not recover even after ten consecutive fluid delivery pulses. Consequently, the count continues to increase and, for this example, the upper count limit is eventually reached. At that time, the fluid infusion device would generate an appropriate alert, alarm, or warning message, as described previously.

Adaptive Occlusion Detection

The force sensor **126** in the fluid infusion device **100** may also be used for purposes of occlusion detection. Most conventional occlusion detection schemes function by triggering an occlusion alarm when a certain preset threshold force is reached. For example, if the typical actuation force for a fluid reservoir is about one pound and the occlusion threshold is three pounds, a detected force that exceeds three pounds will initiate an alert or an alarm. In fluid infusion devices that are occluded, the force might increase by only fractions of a pound per unit of fluid (e.g., insulin) desired to be delivered. As a result, there can potentially be long wait times before an occlusion is actually confirmed.

In contrast, the technique described here is adaptive in nature, and occlusions can be determined prior to reaching the preset threshold by evaluating consecutive rates of change (slopes) of force. For example, assume that the typical force variation in a reservoir is only about 0.02 pound per unit (lb/U) over three or four delivery strokes or pulses. If an occlusion is present, the detected force might increase at a calculated rate of 0.30 lb/U over four consecutive pulses. If the fluid infusion device detects an occlusion, then an alarm might be generated and/or the occlusion force threshold might be adjusted downward by a certain amount. For example, if the normal occlusion threshold is three pounds, a detected occlusion condition might result in a downward adjustment of the occlusion threshold by thirty percent, resulting in an adjusted occlusion threshold of about two pounds. The adaptive approach enables the fluid infusion device to quickly detect an occlusion, relative to traditional methods that only use a static force threshold.

FIG. **13** is a flow chart that illustrates an embodiment of an occlusion detection process **900** for a fluid infusion device, such as the fluid infusion device **100** described above. This embodiment of the process **900** employs an occlusion force threshold, which is consistent with traditional methodologies. Thus, the process **900** may begin by obtaining, calculating, or retrieving the occlusion force threshold (task **902**). In typical implementations this occlusion force threshold is about 2.4 pounds, although the actual amount may vary from one embodiment to another.

In practice, the process **900** can be performed whenever a fluid reservoir is installed into the fluid infusion device. Accordingly, the process **900** may confirm the initial seating and/or priming of the fluid reservoir (task **904**), and then activate a fluid delivery operation, which in turn actuates the fluid reservoir with the drive motor assembly (task **906**). As described in more detail above, actuation of the fluid reservoir causes an amount of force to be imparted to the force sensor. Accordingly, the process **900** determines and saves actuation forces for a designated number of delivery strokes (task **910**). This particular embodiment determines and saves actuation forces for a plurality of consecutive delivery strokes and then determines an average actuation force for the plurality of delivery strokes (task **912**).

The process **900** may continue by comparing the average actuation force (F_{AVE}) to the occlusion force threshold (F_T) obtained at task **902**. If the average actuation force is greater than the occlusion force threshold (query task **914**), then the fluid infusion device initiates and executes appropriate corrective action (task **916**). The corrective action taken by the fluid infusion device may include, without limitation, one or more of the actions described above for the process **200** (see FIG. **5**). If, however, query task **914** determines that the average actuation force is not greater than the occlusion force threshold, then the process **900** continues.

The process may continue by analyzing the actuation force and the amount of fluid (typically expressed as a number or fraction of units) that is desired to be administered for delivery (task **918**). As mentioned above, the process **900** analyzes the rate of change of a metric corresponding to the amount of detected force per unit of fluid (as commanded by the fluid infusion device). In this regard, the process **900** may compute this metric (e.g., in lb/U) in an ongoing manner during the fluid delivery operation. Moreover, the process **900** calculates the rate of change of this metric in an ongoing manner during the fluid delivery operation. Consequently, if the fluid infusion device determines that the rate of change exceeds a predetermined maximum value (query task **920**), then the process **900** leads to task **916** and initiates appropriate corrective action. If, however, query task **920** determines that the rate of change does not exceed the maximum value, then the process **900** assumes that the fluid delivery path is not occluded. Accordingly, the process **900** returns to task **910** to continue monitoring actuation forces for the current fluid delivery operation (and for subsequent fluid delivery operations). The maximum tolerable rate of change may be a fixed value or it may be adaptive in nature. In typical embodiments, the maximum rate of change value will be about 1.0 lb/unit, although different values could be used depending upon the embodiment.

It should be appreciated that the process **900** may be practiced in conjunction with conventional occlusion detection schemes if so desired. For example, one or more of the occlusion detection approaches described in U.S. Pat. Nos. 6,485,465 and 7,621,893 (or modified versions thereof) could be employed with the process **900**.

While at least one exemplary embodiment has been presented in the foregoing detailed description, it should be appreciated that a vast number of variations exist. It should also be appreciated that the exemplary embodiment or embodiments described herein are not intended to limit the scope, applicability, or configuration of the claimed subject matter in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient road map for implementing the described embodiment or embodiments. It should be understood that various changes can be made in the function and arrangement of elements without departing from the scope defined by the claims, which includes known equivalents and foreseeable equivalents at the time of filing this patent application.

What is claimed is:

1. A device for delivering fluid to a user, the device comprising:

a housing; a reservoir cavity within the housing to accommodate fluid reservoirs;

a drive motor assembly in the housing to regulate delivery of fluid by actuating a piston of a fluid reservoir;

a force sensor associated with the drive motor assembly to generate output levels in response to force imparted thereto; and

an electronics module coupled to the force sensor to process the output levels to determine a seating status of the fluid reservoir in the reservoir cavity, wherein the electronics module:

maintains a count that is indicative of the seating status;

stores an adaptive reference force value that corresponds to a previously recorded measure of actuation force imparted to the force sensor during a previous fluid delivery pulse;

obtains a current measure of actuation force imparted to the force sensor for a current fluid delivery pulse;

changes the count when the current measure of actuation force is less than the difference between the adaptive reference force value and a threshold force value, resulting in an updated count; and

generates a seating status alert when the updated count satisfies predetermined alert criteria.

2. The device of claim **1**, wherein the previous fluid delivery pulse and the current fluid delivery pulse are consecutive fluid delivery pulses.

3. The device of claim **1**, wherein the electronics module:

resets the count when the current measure of actuation force is not less than the difference between the adaptive reference force value and the threshold force value;

stores the current measure of actuation force as the adaptive reference force value when the current measure of actuation force is less than an upper threshold force value, wherein the upper threshold force value corresponds to an expected maximum actuation force for the fluid reservoir; and

leaves the adaptive reference force value unchanged when the current measure of actuation force is not less than the upper threshold force value.

4. The device of claim **1**, wherein the threshold force value corresponds to an expected maximum variation in actuation force for the fluid reservoir.

5. The device of claim **1**, wherein the current measure of actuation force represents an average of a plurality of repeated measures of actuation force imparted to the force sensor for the current fluid delivery pulse.

6. The device of claim **1**, wherein the electronics module changes the count by increasing or decreasing the count by an amount that is influenced by a volume of fluid to be delivered by a subsequent fluid delivery pulse.

7. The device of claim **1**, wherein the electronics module changes the count by increasing or decreasing the count by an amount that is influenced by a volume of fluid delivered by a previous fluid delivery pulse.

8. The device of claim **1**, wherein the electronics module changes the count by increasing or decreasing the count by an amount that is influenced by a volume of fluid delivered by the current fluid delivery pulse.

9. The device of claim **1**, wherein the threshold force value is fixed during an operating lifespan of the fluid infusion device.

10. The device of claim **1**, wherein the electronics module resets the count when the current measure of actuation force is not less than the difference between the adaptive reference force value and the threshold force value.

11. The device of claim **10**, further comprising a memory element coupled to the electronics module, wherein the memory element stores the current measure of actuation force as the adaptive reference force value when the current measure of actuation force is not less than the difference between the adaptive reference force value and the threshold force value.

12. A device for delivering fluid to a user, the device comprising:

a housing; a reservoir cavity within the housing to accommodate fluid reservoirs;

a drive motor assembly in the housing to regulate delivery of fluid by actuating a piston of a fluid reservoir;

a force sensor associated with the drive motor assembly to generate output levels in response to force imparted thereto; and

an electronics module coupled to the force sensor to process the output levels to determine a seating status of the fluid reservoir in the reservoir cavity, wherein the electronics module:

obtains measures of actuation force imparted to the force sensor for a number of consecutive fluid delivery pulses;

calculates a pulse-to-pulse difference between two consecutive fluid delivery pulses, the pulse-to-pulse difference based on respective measures of actuation force for the two consecutive fluid delivery pulses; and

initiates corrective action for the fluid infusion device when the pulse-to-pulse difference is greater than a threshold amount of force.

13. The device of claim **12**, wherein the threshold amount of force corresponds to an expected maximum variation in actuation force for the fluid reservoir.

14. The device of claim **12**, wherein the electronics module maintains a count that is indicative of the seating status, and wherein the electronics module initiates the corrective action by:

changing the count by a designated amount, resulting in an updated count;

checking whether the updated count satisfies predetermined alert criteria; and

generating an alert at the device when the updated count satisfies the predetermined alert criteria.

15. The device of claim **14**, wherein the electronics module changes the count by increasing or decreasing the count by an amount that is influenced by a volume of fluid to be delivered by a subsequent delivery pulse.

16. The device of claim **12**, wherein:

the pulse-to-pulse difference is calculated for a first fluid delivery pulse and a second fluid delivery pulse;

the electronics module calculates a subsequent pulse-to-pulse difference for the second fluid delivery pulse and a third fluid delivery pulse, the subsequent pulse-to-pulse difference based on respective measures of actuation force for the second fluid delivery pulse and the third fluid delivery pulse;

the first fluid delivery pulse, the second fluid delivery pulse, and the third fluid delivery pulse are consecutive fluid delivery pulses; and

the electronics module resets the count when the subsequent pulse-to-pulse difference is not greater than the threshold force value.

17. The device of claim **12**, wherein the threshold force value is fixed during an operating lifespan of the device.

18. A device for delivering fluid to a user, the device comprising:

a housing; a reservoir cavity within the housing to accommodate fluid reservoirs;

a drive motor assembly in the housing to regulate delivery of fluid by actuating a piston of a fluid reservoir;

a force sensor associated with the drive motor assembly to generate output levels in response to force imparted thereto; and

an electronics module coupled to the force sensor to process the output levels to determine a seating status of the fluid reservoir in the reservoir cavity, wherein the electronics module:

obtains a baseline actuation force imparted to the force sensor, after initial seating and priming of the fluid reservoir;

determines a measured actuation force imparted to the force sensor, the measured actuation force corresponding to a designated delivery stroke of the drive motor assembly; and

generates indicia of an unseated reservoir condition when the measured actuation force is less than the baseline actuation force by at least a predetermined amount of force.

19. The device of claim **18**, wherein the electronics module updates the baseline actuation force as a function of the measured actuation force when the measured actuation force is not less than the baseline actuation force by at least the predetermined amount of force.

20. The device of claim **18**, further comprising a memory element coupled to the electronics module, wherein the electronics module saves the measured actuation force in the memory element for use as an updated baseline actuation force.

21. The device of claim **18**, wherein the predetermined amount of force is fixed during an operating lifespan of the device.

22. The device of claim **18**, wherein the electronics module:

detects that the measured actuation force is less than the baseline actuation force by at least the predetermined amount of force; and

thereafter, determines a second measured actuation force imparted to the force sensor, the second measured actuation force corresponding to a subsequent delivery stroke of the drive motor assembly that occurs after the designated delivery stroke;

wherein the indicia of the unseated reservoir condition is generated when the measured actuation force and the second measured actuation force are both less than the baseline actuation force by at least the predetermined amount of force.

23. The device of claim **22**, wherein the subsequent delivery stroke of the drive motor assembly occurs a predetermined number of delivery strokes after the designated delivery stroke.

24. A device for delivering fluid to a user, the device comprising:

a housing; a reservoir cavity within the housing to accommodate fluid reservoirs;

a drive motor assembly in the housing to regulate delivery of fluid by actuating a piston of a fluid reservoir;

a force sensor associated with the drive motor assembly to generate output levels in response to force imparted thereto; and

an electronics module coupled to the force sensor to process the output levels to determine a seating status of the fluid reservoir in the reservoir cavity, wherein the electronics module:

confirms initial seating of the fluid reservoir in the reservoir cavity;

determines a measure of actuation force imparted to the force sensor during a fluid delivery action of the drive motor assembly;

compares the measure of actuation force to an amount of force that is less than normally expected actuation forces of the device, the amount of force being indicative of an unseated state of the fluid reservoir; and

initiates corrective action for the device when the measure of actuation force is less than the amount of force.

25. The device of claim **24**, further comprising a memory element coupled to the electronics module to store the amount of force as a fixed quantity during an operating lifespan of the device.

26. The device of claim **24**, wherein the drive motor assembly regulates delivery of fluid from the device using discrete delivery strokes, and wherein the electronics module determines the measure of actuation force by:

determining a plurality of actuation forces imparted to the force sensor during a plurality of consecutive delivery strokes; and

calculating an average actuation force based upon the plurality of actuation forces, the measure of actuation force being equal to the average actuation force.

27. The device of claim **24**, further comprising a memory element coupled to the electronics module, wherein the electronics module:

obtains a nominal expected actuation force;

calculates the amount of force as a function of the nominal expected actuation force; and

stores the amount of force in the memory element.

28. The device of claim **27**, wherein the amount of force is calculated to be less than the nominal expected actuation force by at least ten percent of the nominal expected actuation force.

29. The device of claim **27**, wherein the amount of force is calculated to be at least 0.15 pounds less than the nominal expected actuation force.

30. A device for delivering fluid to a user, the device comprising:

a housing; a reservoir cavity within the housing to accommodate fluid reservoirs;

a drive motor assembly in the housing to regulate delivery of fluid by actuating a piston of a fluid reservoir;

a force sensor associated with the drive motor assembly to generate output levels in response to force imparted thereto; and

an electronics module coupled to the force sensor to process the output levels to determine a seating status of the fluid reservoir in the reservoir cavity, wherein the electronics module:

obtains a baseline actuation force imparted to the force sensor, after initial seating and priming of the fluid reservoir;

determines a measured actuation force imparted to the force sensor, the measured actuation force corresponding to a designated delivery stroke of the drive motor assembly; and

generates indicia of an unseated reservoir condition when the measured actuation force is less than the baseline actuation force by at least a predetermined amount.

31. The device of claim **30**, further comprising a memory element coupled to the electronics module to store the baseline actuation force.

32. The device of claim **31**, wherein the electronics module updates the baseline actuation force as a function of the measured actuation force when the measured actuation force is not less than the baseline actuation force by at least the predetermined amount.

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